IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CAREFIRST OF MARYLAND, INC., *et al., on behalf of themselves and all others similarly situated*, Plaintiffs, v. JOHNSON & JOHNSON *and* JANSSEN BIOTECH, INC., Defendants.	Case No. 2:23-cv-629

MEMORANDUM OPINION & ORDER

Before the Court are the Motion to Dismiss and Motion to Stay filed by Defendants Johnson & Johnson ("J&J") and Janssen Biotech, Inc. ("Janssen") (collectively "defendants"). ECF Nos. 45 (motion to dismiss), 46 (memorandum), 47 (motion to stay), 48 (memorandum).[1] The Court has considered the arguments in the parties' briefing and concluded there is no need to hold a hearing on the motions. *See* Fed. R. Civ. P. 78(b); E.D. Va. Civ. R. 7(J). For the reasons stated herein, the motion

[1] On June 17, 2024, the Court ordered the parties to file supplemental briefing on the issue of antitrust standing. ECF No. 89. Defendants filed their supplemental brief on July 1, 2024. ECF No. 92. Plaintiffs filed their supplemental brief on July 17, 2024. ECF No. 98.

to dismiss is **GRANTED IN PART** and **DENIED IN PART**, and the motion to stay is **DENIED AS MOOT**.[2]

I. BACKGROUND

A. Regulatory Background

The Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262, governs the approval of both new biologic drugs and biosimilars.[3] The BPCIA requires a biologic manufacturer to submit a Biologic License Application ("BLA") to the Food and Drug Administration ("FDA") before it can market its drug. 42 U.S.C. § 262(a). For biosimilars, the BPCIA provides a condensed FDA approval process. *See* 42 U.S.C. §§ 262(i)(2), 262(k)(2)(A). To obtain approval, a biosimilar manufacturer can submit an abbreviated BLA demonstrating that its biosimilar is "highly similar" to the reference biologic and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency." 42 U.S.C. §§ 262(i)(2)(A)–(B). This shortened process is available to biosimilar manufacturers 12 years after the reference biologic first obtained its license. 42 U.S.C. § 262(k)(7)(A).

The BPCIA also allows the FDA to designate a biosimilar as "interchangeable." 42 U.S.C. § 262(i)(3). An interchangeable biosimilar can "be substituted for the

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[2] Defendants requested that the Court stay discovery while the motion to dismiss is pending. ECF No. 48 at 1. In this Memorandum Opinion and Order, the Court is ruling on the motion, which moots the motion to stay because the motion to dismiss is no longer pending.

[3] Biologics, sometimes referred to as biopharmaceuticals, are drugs that are derived from biological sources, such as animals or microorganisms. A vaccine, for example, is a biologic drug. Biosimilars are copies of biologic drugs.

reference product without the intervention of the health care provider[s] who prescribed the reference product." *Id.* To obtain this designation, the biosimilar manufacturer must demonstrate to the FDA that its product "is biosimilar to the reference product [and] can be expected to produce the same clinical result as the reference product in any given patient." 42 U.S.C. § 262(k)(4)(A).

B. Factual Background

At this stage of the litigation, the Court assumes that all facts alleged in the Amended Complaint are true. The crux of this dispute is whether defendants' enforcement of their method-of-use patent for ustekinumab and their acquisition of patents from Momenta constitutes a violation of § 2 of the Sherman Act. Ustekinumab is a biologic drug that treats various autoimmune diseases including moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn's disease, and moderate to severe ulcerative colitis. ECF No. 36 ¶ 91. J&J first applied for a patent covering composition of matter for ustekinumab in 2001. *Id.* ¶ 98. The PTO granted the composition patent in 2005 ("the '734 patent"). *Id.* ¶ 99. After receiving FDA approval in 2009, J&J began selling ustekinumab under the brand name Stelara to treat moderate to severe plaque psoriasis. *Id.* ¶ 101. Then, after receiving additional FDA approval, J&J sold Stelara to treat psoriatic arthritis in 2013 and Crohn's disease in 2016. *Id.* ¶¶ 102–03. The '734 patent expired on September 25, 2023. *Id.* ¶ 3.

In 2019, J&J filed another patent application, seeking a method-of-use patent covering ustekinumab to treat moderate to severe ulcerative colitis, claiming a

priority date of September 24, 2018. ECF No. 36 ¶ 132. J&J announced its proposal for a Phase 3 clinical trial, "NCT 236," for testing the use of ustekinumab to treat ulcerative colitis on April 2, 2015. *Id.* ¶ 120. A year later, J&J concluded in NCT 236 that "considering the similarities in the genetics and biology of [ulcerative colitis] and Crohn's disease, it is reasonable to assume that ustekinumab will also be effective in" treating ulcerative colitis. *Id.* ¶ 122. And J&J used these safety results as a justification for skipping Phase 2 trials. *Id.* In the patent prosecution, J&J stated that it would not have been obvious that ustekinumab would have effectively treated ulcerative colitis. *Id.* ¶ 143. And J&J also claimed that NCT 236 "did not disclose or suggest that treating [ulcerative colitis] with ustekinumab would achieve a response as measured by any one of the seven known endpoints measures for ulcerative colitis treatment." *Id.* ¶ 147. Both statements were false. *Id.* And other studies, published before J&J's statements in the patent prosecution, acknowledged the efficacy of ustekinumab to treat ulcerative colitis. ECF No. 36 ¶ 140.

Because the patent application process is *ex parte*, federal regulation requires patent applicants to be as forthcoming as possible with patent examiners regarding prior art. ECF No. ¶ 63. In the application, J&J's attorney falsely represented that "[p]rior to the present invention, no studies had been conducted with ustekinumab for [ulcerative colitis]." *Id.* ¶ 140. And J&J's attorney omitted Spanish, German, and/or Swiss studies from the patent examiner. *Id.* On July 26, 2020, the patent examiner rejected the application as either anticipated by a study or obvious. *Id.* ¶ 141. In response, J&J's attorney contacted the patent examiner and stated that, as

of September 2018, "it would not have been obvious" that ustekinumab would successfully treat ulcerative colitis. *Id.* ¶ 143. And J&J updated the patent application's claims and reiterated that they were not anticipated or rendered obvious by the referenced study. *Id.* ¶ 147. The PTO subsequently issued a method-of-use patent ("the '307 patent") on March 30, 2021. *Id.* ¶ 151.

In 2020, J&J acquired Momenta Pharmaceuticals, Inc. ("Momenta"). ECF No. 36 ¶ 162. Momenta was an independent biotechnology company that developed therapeutics for autoimmune diseases. *Id.* ¶ 155. It focused on developing biosimilar and complex generic products. *Id.* Momenta obtained four patents covering its biosimilar manufacturing technologies that use cell culturing processes to target and control features of biosimilar antibodies to assure equivalence to reference products. *Id.* ¶ 158. In essence, Momenta's technologies enhance the ability to produce a biosimilar product that the FDA would approve to compete with the biosimilar's reference product. Thus, the technology is "of particular use to biosimilar developers" because it "can be used to manufacture products more likely to obtain an 'interchangeability' determination from the FDA," which speeds up the process of getting a biosimilar to market. *Id.* ¶ 164. The acquisition gave J&J exclusive rights to Momenta's four biosimilar manufacturing patents. *Id.* ¶ 162.

J&J then enforced the '307 patent and the patents it acquired from Momenta against biosimilar competitors. ECF No. 36 ¶ 246. In anticipation of the expiration of the '734 patent, several biosimilar competitors launched Phase 3 interchangeability clinical trials. *Id.* ¶ 182. Amgen, the first biosimilar competitor, completed its Phase

3 trial on June 3, 2022. *Id.* ¶ 184. After engaging in the "patent dance," J&J ultimately sued Amgen for infringement of the '734 composition patent, the '307 method-of-use patent, and the four Momenta patents. *Id.* ¶¶ 189–191, 195. J&J then moved for a preliminary injunction relying solely on two of the four Momenta patents. *Id.* ¶ 196. Amgen and J&J ultimately reached an agreement and settled the case. *Id.* ¶ 198. The FDA approved Amgen's biosimilar on October 31, 2023, but pursuant to its agreement with J&J, Amgen will not launch its product until January 1, 2025. *Id.* ¶¶ 198, 200. J&J has entered into several other settlement agreements with biosimilar competitors including Samsung Bioepis, Alvotech Holdings and Teva Pharmaceuticals, Fresenius Kabi and Formycon AG, Celltrion, and Accord BioPharma. *Id.* ¶ 231. Consequently, purchasers of ustekinumab "have paid, and will continue to pay, supra-competitive prices." *Id.* ¶ 248.

As a result, Plaintiffs Carefirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., Carefirst Bluechoice, Inc., and CFA, LLC[4] (collectively "plaintiffs"), filed a putative class action on December 7, 2023. ECF No. 1. Plaintiffs subsequently amended their complaint on February 5, 2024. ECF No. 36. The Amended Complaint contains six claims against defendants:

- Count 1: Monopolization in Violation of Section 2 of the Sherman Act,
- Count 2: Attempted Monopolization in Violation of Section 2 of the Sherman Act,

[4] CFA, LLC filed a Notice of Voluntary Dismissal on June 27, 2024. Thus, it is no longer a party to the case.

- Count 3: Monopolization and Monopolistic Scheme Under State Law,
- Count 4: Attempted Monopolization Under State Law,
- Count 5: Violations of State Consumer Protection Laws, and
- Count 6: Unjust Enrichment Under State Law.

Id. at 91–138. Defendants filed the instant motion to dismiss on March 5, 2024, and the motion to stay on March 6, 2024. ECF Nos. 45, 47.[5]

II. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In other words, a plaintiff must plead sufficient "factual content [that] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's belief of a complaints factual allegations." *Neitzke v. Williams*, 490 U.S. 319, 327 (1989). But "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Twombly*, 550 U.S. at 545. When considering a motion to dismiss, the court "must take all factual allegations in the complaint as true," but the

[5] This Court uses the page numbers assigned by CM/ECF rather than documents' internal pagination.

court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papsan v. Allain*, 478 U.S. 265, 286 (1986).

III. ANALYSIS

A. Federal Antitrust Claims—Monopolization and Attempted Monopolization, in violation of 15 U.S.C. § 2

Section 2 of the Sherman Act states that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person . . . to monopolize any part of the trade" is subject to penalties. 15 U.S.C. § 2. To state either a monopolization or an attempted monopolization claim, a plaintiff must demonstrate (1) either monopoly power or a dangerous probability of obtaining such power in the relevant market and (2) anticompetitive or exclusionary conduct. *Kolon Indus. Inc. v. E.I. du Pont de Nemours and Co.*, 748 F.3d 160, 173, 177 (4th Cir. 2014). Essentially, a claimant must allege that the opposing party used its monopoly power to foreclose or destroy competition or gain an advantage, or gained or maintained its power not from a superior product or business acumen. *United States v. Griffith*, 334 U.S. 100, 107 (1948). Simply put, a § 2 violation has two elements: power and conduct. The Court will address each element in turn.

i. Monopoly Power

"Monopoly power is the power to control prices or exclude competition." *Kolon Indus. Inc.*, 748 F.3d at 173 (quotation marks and citation omitted). A defendant has market power "if it can raise price[s] above the competitive without a total loss of sales." 14 Philip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 501 (2024). Market power exists in

degrees, and a defendant has "large" market power when it "can profit by raising prices substantially without losing too many sales." *Id.* There is no fixed percentage market share that conclusively resolves whether monopoly power exists; however, the United States Supreme Court has never found a party with less than 75% market share to have monopoly power, and the United States Court of Appeals for the Fourth Circuit has observed that "when monopolization has been found the defendant controlled [70] to [100] percent of the relevant market." *Id.* at 174 (quotation marks and citations omitted).

The Amended Complaint alleges—and defendants do not dispute—that the relevant market is the United States market for ustekinumab. ECF No. 36 ¶¶ 362–63. It further alleges that since Stelara's entry, defendants have never lowered the price or lost sales volume. *Id.* ¶ 266. While there are other biologics that can treat ulcerative colitis, Crohn's disease, plaque psoriasis, and psoriatic arthritis, the Amended Complaint alleges that they are not interchangeable with ustekinumab. *Id.* ¶¶ 270–73; *see E.I. du Point de Nemours*, 637 F.3d at 442 ("Courts consider, in this context, the availability—or lack thereof—of alternative supplies to which a consumer might practicably turn because alternative supplies constrain an alleged monopolist's ability to raise prices or exclude competition."). Because the Amended Complaint alleges that defendants control a dominant share of the defined relevant

market and have demonstrated a power to control prices, it sufficiently alleges that at all relevant times defendants had a monopoly. *Kolon Indus. Inc.*, 748 F.3d at 173.[6]

ii. Anticompetitive Conduct

Next, plaintiffs must allege unlawful use of monopoly power. The Amended Complaint alleges an anticompetitive scheme comprised of defendants' unlawful enforcement of the '307 patent and acquisition of the Momenta patents. The Fourth Circuit recently provided guidance on how courts should approach allegations of a broad antitrust scheme. Specifically, the Fourth Circuit reiterated that "[i]t is foundational that alleged anticompetitive conduct must be considered as a whole." *Duke Energy Carolinas, LLC v. NTE Carolinas II, LLC*, No. 22-2168, 2024 WL 3642432, at *11 (4th Cir. Aug. 5, 2024). The Fourth Circuit then highlighted a distinction between anticompetitive conduct that falls within well-defined categories

[6] Defendants dispute their monopoly power. ECF No. 46 at 2; ECF No. 65 at 1 n.1. There are two ways to challenge monopoly power: either challenging the alleged market power or the definition of the relevant market itself. Defendants do neither. It cannot be true that simply stating a "dispute" as to an argument, without more, constitutes addressing the merits of that argument. *See Amazon.com, Inc. v. WDC Holdings, LLC*, No. 1:20-cv-484, 2023 WL 2815140, at *11 (E.D. Va. Apr. 6, 2023) (finding an argument conceded because the party's opposition did not respond to the argument); *Intercarrier Commc'ns, LLC v. Kik Interactive, Inc.*, No. 3:12-cv-771, 2013 WL 4061259, at *1 (E.D. Va. Aug. 9, 2013) (concluding that where a party fails to respond to an argument it is "effectively conceding the argument"); *Cureton v. U.S. Marshal Serv.*, 322 F. Supp. 2d 23, 27 (D.D.C. 2004) ("When a plaintiff files a response to a motion to dismiss but fails to address certain arguments made by the defendant, the court may treat those arguments as conceded, even when the result is dismissal of the case."). This alone is sufficient for the Court to find that the Amended Complaint alleges monopoly power for purposes of the instant motion. However, the Court also finds that the facts, as alleged, are sufficient.

where "the case law has developed tests for analyzing such claims" and allegations "of a complex or atypical exclusionary campaign" that cannot be categorized. *Id.* If a complaint alleges the former type of scheme, then assessing the lawfulness of each claim independently "is a proper approach." *Id.* But if it alleges the latter, then "application of such specific conduct tests would prove too rigid." *Id.* But, in both instances, courts "must not dismember the individual acts of an exclusionary campaign when those acts are interconnected." *Id.* at 12. The Court will discuss each component of the scheme separately because of the complex factual allegations related to each. However, because plaintiffs have alleged a scheme, and consistent with Fourth Circuit case law, the Court will consider each "as part of a single campaign to foreclose competition." *Id.* at 13.

Each component of the alleged scheme involves defendants exercising their rights under the patent laws. There is an obvious and well-documented tension between patent laws and antitrust laws. *E.g., Int'l Wood Processors v. Power Dry Inc.*, 792 F. 2d 416, 426 (4th Cir. 1986). The former grants patent owners the right to exclude competitors from the relevant market and encourages monopolies, whereas the latter prohibits monopolies and encourages competition. Courts are clear that antitrust laws do not "require a patent holder to forfeit the exclusionary power inherent in [their] patent the instant [their] patent monopoly affords [them] monopoly power over the relevant market." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981). However, the enforcement and acquisition of patents are "not immune from [] antitrust laws." *Id.* at 1205; *see also Ford Motor Co. v. United States*,

405 U.S. 562, 576 n.11 (1972) ("Even constitutionally protected property rights such as patents may not be used as levers for obtaining objectives proscribed by the antitrust laws.") (citations omitted). The Court will first consider the allegation that defendants acquired the '307 patent by fraud, and then will examine the acquisition of the Momenta patents.

a. The Enforcement of the '307 Patent

The *Noerr-Pennington* doctrine shields private entities from antitrust liability when enforcing patents. *See Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, 483 F. Supp. 3d 38, 54 (D. Mass. 2020) ("As a result, the *Noerr-Pennington* doctrine bars this Court from regarding litigation brought in good[]faith as anticompetitive harm."). However, there are two exceptions to this general rule. A patent holder is not shielded from antitrust liability when (1) it obtained a patent through fraud or (2) the patent litigation is a sham. *Walker Process Equip. Inc., v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965); *Prof. Real Estate Invs. Inc. v. Columbia Pictures Indus.,* 508 U.S. 49, 51 (1993).

The fraudulent procurement exception—commonly referred to as *Walker Process* fraud—requires a showing that the patentee obtained their patent by "knowingly and willfully misrepresenting facts to the [PTO]." *Walker Process Equip. Inc.*, 382 U.S. at 177. The United States Court of Appeals for the Federal Circuit[7] has

[7] "Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998).

consistently construed *Walker Process* as requiring common-law fraud. Thus, a plaintiff must show:

> (1) a false representation or deliberate omission of a fact material to patentability,
>
> (2) made with the intent to deceive the patent examiner,
>
> (3) on which the patent examiner justifiably relied in granting the patent, and
>
> (4) but for which misrepresentation or deliberate omission the patent would not have been granted.

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1070–71 (Fed. Cir. 1998).[8]

1. Antitrust Standing

As a threshold matter, the Court must determine whether plaintiffs, as indirect purchasers, have standing to bring a *Walker Process* fraud claim. The Supreme Court has interpreted the broad language of the Clayton Act to require antitrust plaintiffs to go beyond a showing that they meet the Article III standing requirements and additionally show "antitrust standing." *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 310 (4th Cir. 2007); *see Assoc. Gen. Contractors v. Cal. State*

[8] Fraud claims are subject to a heightened pleading standard that requires "stat[ing] with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783–84 (4th Cir. 1999). This heightened standard requires facts establishing the "who, what, when, where, and how" of the claimed fraud. *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008). However, "malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). In other words, "conclusory allegations of defendant's knowledge as to the true facts and of defendant's intent to deceive." *Harrison*, 176 F.3d at 784.

Council of Carpenters, 459 U.S. 519 (1983) (hereinafter "*AGC*") ("Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action . . . ."). Here, defendants argue that plaintiffs lack antitrust standing to pursue their claims for equitable relief under federal law. ECF No. 46 at 19–20. The Fourth Circuit has not determined whether indirect purchasers of patented products have standing to assert a *Walker Process* fraud claim.

The issue of who has standing to bring a *Walker Process* claim has divided courts. Some have found that only competitors against whom the patent could be enforced have standing. *E.g., Walgreen Co. v. Organon Inc. (In re Remeron Antitrust Litg.)*, 335 F. Supp. 2d 522, 529 (D.N.J. 2004) ("Plaintiffs, as direct purchasers, neither produced [the patented product] nor would have done so . . . Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim."). Whereas others have found that direct consumers have standing. *E.g., Molecular Diagnostics Labs. v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 281 (D.D.C. 2005) ("Examining [the antitrust standing factors], the court sees no reason to limit standing to competitors.").

Another has taken a middle ground—finding that direct consumers have standing only when the patent has already been deemed invalid. *Meijer Inc. v. Ferring B.V. (In re DDAVP Direct Purchaser Antitrust Litig.*), 585 F.3d 677, 691–92 (2d. Cir. 2009) ("[W]e . . . hold only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct."). And no court has explicitly found that indirect purchasers have standing

to bring a *Walker Process* fraud claim. *Farag v. Health Care Serv. Corp.*, No. 1:17-cv-2547, 2017 WL 2868999, at *5 (N.D. Ill. July 5, 2017); *In re K-Dur Antitrust Litig.*, No. 1:1-cv-1652, 2007 WL 5297755, at *17 (D.N.J. Mar. 1, 2007); *Ryan-House v. Glaxosmithkline, PLC*, No. 2:02-cv-442, 2004 WL 7390565, at *3–4 (E.D. Va. Mar. 11, 2004) (assuming without deciding the indirect-purchaser plaintiffs had standing to bring *Walker Process* fraud claims for injunctive relief).

None of these cases address the narrow question before the Court—whether indirect purchasers have standing to bring a *Walker Process* claim for injunctive relief—because each case dealt with claims for damages pursuant to § 4 of the Clayton Act. There are important differences between § 4 and § 16 of the Clayton Act. *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 111 (1986) ("It is plain that § 16 and § 4 differ in various ways."). There is a difference in the available remedy—§ 4 allows for treble damages whereas § 16 allows only for an injunction. *Id.* And the relief sought pursuant to § 4 requires proof of loss, whereas relief under § 16 requires only a threat of loss. *Id.*

These differences mean that the "standing analysis under § 16 will not always be identical to standing analysis under § 4." *Cargill, Inc.*, 479 U.S. at 111 n.6. Standing under § 4 requires consideration of several factors[9] "[i]n order to protect against multiple lawsuits," including "the potential for duplicative recovery, complexity of appropriating damages, and the existence of other parties that have been more directly harmed." *Id.* (citing *AGC*, 459 U.S. at 544–45 and *Illinois Brick*

[9] The five factors that courts must consider are discussed at length in Part III.B.a.1.

Co., 431 U.S. 720, 730–31 (1977)). Equitable remedies do not raise a threat of duplicative recovery because "one injunction is as effective as 100." *Id.* (citing *Hawaii v. Standard Oil. Co.*, 405 U.S. 251, 261 (1972)). Because of these differences, the Supreme Court has concluded that "some of the factors other than antitrust injury that are appropriate to a determination of standing under § 4 are not relevant under § 16." *Id.*; *Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1452 (11th Cir. 1991) (stating that "the essential difference" between § 4 and § 16 standing inquiries is that "courts are less concerned about whether the plaintiff is an efficient enforcer of the antitrust laws when the remedy is equitable because the dangers of mismanaging the antitrust laws are less pervasive in this setting").

The Fourth Circuit has stated that indirect purchasers are not *per se* barred from bringing a claim for injunctive relief. *Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 n.24 (4th Cir. 2002) ("*Illinois Brick*'s indirect purchaser rule, when applicable, bars only compensatory damages relief and does not apply to injunctive relief.") (citing *Cargill, Inc.*, 479 U.S. at 111 n.6, *Campos v. Ticketmaster*, 140 F.3d 1166, 1172 (8th Cir. 1998), and *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 856–57 (3d Cir. 1996)). The lack of a *per se* bar does not, however, relieve plaintiffs of their obligation to demonstrate standing. While standing under § 16 is not as demanding as § 4 standing, it does require a showing of antitrust injury, or rather, "injury of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful." *Cargill, Inc.*, 479 U.S. at 489; *see also In re Interior Molded Doors Antitrust Litig.*, No. 3:18-cv-718, 2019 WL 4478734, at * 9 (E.D. Va.

Sept. 18, 2019) (stating that the court "will focus on the [antitrust injury] in analyzing the indirect purchaser plaintiffs' claim for injunctive relief under the Sherman Act").

Plaintiffs' alleged injury—the payment of supra-competitive prices for ustekinumab—is undoubtably an injury that the antitrust laws were intended to prevent. The Supreme Court has stated that the legislative history of the Clayton Act "shows that Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices by the giant trusts and combinations that dominated certain interstate markets." *AGC*, 459 U.S. at 530. In other words, preventing customers from paying supra-competitive prices is the principal purpose of the antitrust laws. *Kocher v. Greater Lafayette Health Servs., Inc.*, 463 F.3d 710, 716 (7th Cir. 2006) (observing that "the principal purpose of the antitrust laws is to prevent overcharges to consumers") (cleaned up).

A plaintiff must also allege that the harm "flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). The Supreme Court addressed the relationship between indirect purchasers and causation in *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982). There, the Supreme Court instructed that whether a particular harm is too remote from the violation to constitute an antitrust injury depends on both traditional principals of proximate causation and on "the relationship of the injury alleged with those forms of injury about which Congress was likely to have been concerned" when enacting the antitrust laws. *Id.* at 478. Specifically, the Supreme Court instructed courts to look at whether the indirect purchaser was a foreseeable

victim of the violation. *Id.* at 479; *see also Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 125 (1969) (stating that alleged harm must be "the type of loss that the claimed violations . . . would be likely to cause.").

Here, plaintiffs are foreseeable victims of defendants' alleged antitrust violation. Indeed, the driving force behind keeping biosimilars from entering the ustekinumab market is that a biosimilar entrance would lower the price defendants could charge for Stelara. *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 402 (3d Cir. 2000) ("[Alleged monopolist's] efforts to keep the generic drug off the market emanate from the fact that the introduction of the generic product would force down the price paid for the [brand name drug]."). In other words, plaintiffs' payment of supra-competitive prices is "not only [] inextricably intertwined" with defendants' alleged scheme, "[it is] the aim" of it. *Id.* at 401 (quotation marks omitted). Thus, plaintiffs' injury was more than just foreseeable—"it was a necessary step in effecting the ends of the alleged illegal conspiracy." *McCready*, 457 U.S. at 479. Because plaintiffs have sufficiently alleged an antitrust injury, they have standing to bring a *Walker Process* fraud claim for injunctive relief.

This conclusion is not inconsistent with the case law on *Walker Process* fraud standing. At least part of the reasoning behind courts concluding that only potential infringers had standing to bring a *Walker Process* fraud claim was grounded in patent law, *not* antitrust principles. *E.g., Indium Corp. of Am. v. Semi-Alloys, Inc.*, 566 F. Supp. 1344, 1353 (N.D.N.Y. 1983) (holding that only potential or actual infringers could bring a *Walker Process* fraud claim in part because it "parallels the case and

controversy requirement for declaratory judgment jurisdiction over patent suits"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 542 (E.D.N.Y. 2005) ("It is also apparent that Congress did not intend to change the standing requirement for actions to invalidate patents when it passed . . . the Hatch-Waxman Amendments in 2003."); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d at 529 (relying on *Carrot Components Corp. v. Thomas & Betts Corp.*, No. 1:85-cv-5133, 1986 WL 84373, at *3 (D.N.J. Feb. 3, 1986), which held that only potential or actual infringers could bring a lawsuit for declaratory judgment to challenge a patent's validity).

The same is true for the United States Court of Appeals for the Second Circuit's conclusion that a direct consumer only had standing to sue when a patent was already declared invalid. In fact, the Second Circuit concluded that direct consumers suffered antitrust injury and "would be efficient enforcers under any formulation" of the antitrust standing factors. *In re DDAVP Direct Purchaser Litig.*, 585 F.3d at 688–89. What complicated the matter for the court was that the plaintiffs' claim hinged on the validity of the patent, which, under the patent laws, only a potential or actual infringer can challenge. *Id.* at 690–91.

These decisions came before the Federal Circuit weighed in on the issue in *Ritz Camera & Image, LLC v. Sandisk Corp.*, 700 F.3d 503 (Fed. Cir. 2012). There, the Federal Circuit held that "[n]othing in *Walker Process* supports [concluding] that the rules governing standing to bring patent validity challenges should be imported into an antitrust case." *Id.* at 507. The Federal Circuit further opined that "[a] *Walker*

Process antitrust claim is a separate cause of action from a patent declaratory judgment action . . . [and is] governed by principles of antitrust law." *Id.* at 508. The Federal Circuit's decision severely undercuts the reasoning in these cases.

Further, the cases that have directly dealt with indirect purchaser standing to bring a *Walker Process* fraud claim are likewise inapplicable to this case. Both cases—*Farag v. Health Care Serv. Corp.*, No. 1:17-cv-2547, 2017 WL 2868999 (N.D. Ill. July 5, 2017), and *In re K-Dur Antitrust Litigation*, No. 1:1-cv-1652, 2007 WL 5297755 (D.N.J. Mar. 1, 2007)—involved claims for damages *not* injunctive relief. And each court based its reasoning, at least in part, on factors that are not relevant to determine whether a plaintiff has standing to bring a claim for injunctive relief. *Farag*, 2017 WL 2868999 at *5–6 (finding that the plaintiffs lacked standing because they did not allege an antitrust injury and because there is a risk of duplicative recovery and complex damages); *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *19 ("[T]here is considerable difficulty in determining damages for indirect purchasers. Moreover, because indirect purchasers are two steps removed from the underlying injury (*i.e.,* to competitors), ascertaining their damages is a far more speculative endeavor. Finally, as compared to competitors and direct purchasers, indirect purchasers have certainly been *less* 'directly harmed' than their counterparts.") (quotation marks omitted).

Specifically, the court in *In re K-Dur Antitrust Litigation* was concerned that if it "were to conclude that *indirect* purchasers had standing to bring *Walker Process* claims, it would turn antitrust policy on its head, and extend antitrust standing to an

extraordinary level." 2007 WL 5297755, at *18. The court's reasoning is sound in the context of claims brought under § 4 for damages. Generally, indirect purchasers cannot recover monetary damages. *Illinois Brick Co.*, 431 U.S. at 730–31. That is not true for injunctive relief. *Dickson*, 309 F.3d at 213 n.24. Thus, at least in the Fourth Circuit, this Court's conclusion does not extend antitrust standing any further.

In sum, the Amended Complaint alleges antitrust injury. The alleged harm—the payment of supra-competitive prices for ustekinumab—is an injury that the antitrust laws were designed to prevent. And the Amended Complaint alleges that the payment of these prices was defendants' ultimate goal when enforcing the '307 patent to keep biosimilars off the market. Thus, plaintiffs have standing to bring a *Walker Process* fraud claim under § 16 of the Clayton Act for injunctive relief.

2. Misrepresentation of NCT 236

Now the Court will turn to the merits of plaintiffs' *Walker Process* fraud claim. The allegations in the Amended Complaint relating to the misrepresentation of NCT 236 are summarized as follows: J&J represented to the PTO that "it would not have been obvious . . . ustekinumab would successfully treat ulcerative colitis." ECF No. 36 ¶ 143. However, J&J's clinical trial protocol for the use of Stelara to treat ulcerative colitis (NCT 236) stated that "considering the similarities in the genetics and biology of [ulcerative colitis] and Crohn's disease, it is reasonable to assume that ustekinumab will also be effective in [ulcerative colitis]." *Id.* ¶ 122. During the patent prosecution, J&J also stated that NCT 236 "did not disclose or suggest that treating [ulcerative colitis] with ustekinumab would achieve a response as measured by any

one of the seven known endpoints measures for ulcerative colitis treatment." *Id.* ¶ 147. However, NCT 236 did disclose that fact. *Id.*

Defendants argue that these statements are attorney arguments, not misrepresentations. The Federal Circuit has stated that attempts at distinguishing prior art do not constitute material misrepresentations, as the examiner is free to reach their own conclusion. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986). The boundaries of what distinguishes zealous advocacy from fraud are unclear because, as several courts have pointed out, "defining mere advocacy often proves challenging." *Ronald A. Katz Tech. Licensing, L.P. v. Verizon Comm'n Inc.*, No. 01-cv-5627, 2002 WL 1565483, at *4 (E.D. Pa. July 16, 2002) (collecting cases) (quotation marks omitted).

While defendants' statements certainly skirt the line between zealous advocacy and fraud, the Court need not discern between the two because the statements were not material. The plaintiff must allege facts sufficient to find that "the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (citation omitted). Plaintiffs' allege misrepresentation on the basis that J&J's attorney knew or should have known that "controlling law was clear that public clinical trial disclosure, like NCT 236, can invalidate patent applications." ECF No. 57 at 17; ECF No. 36 ¶ 134. And yet, despite this "well[-]established legal rule," J&J's attorney said that NCT 236 did not render the patent application anticipated or obvious. ECF No. 36 ¶ 134.

However, the Amended Complaint also alleges that the patent examiner had NCT 236 before them. ECF No. 36 ¶ 141. Therefore, the patent examiner was "free to reach his own conclusion and accept or reject" defendants' claims that it did not render the '307 patent obvious. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). To agree with plaintiffs that the misrepresentation was material, the Court would have to infer that the patent examiner was not aware of the well-established legal rule. That is not a reasonable inference. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 n.5 (Fed. Cir. 2009) ("A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objections of candor and good faith.") (citation omitted); *Young*, 492 F.3d at 1349 (determining there was no inequitable conduct because the court "fail[ed] to see how . . . an interpretation of what prior art discloses, constitute[s] affirmative misrepresentations of material fact" when the prior art was available to the patent examiner to refer to).

3. Omission of Relevant Prior Art

Next the Amended Complaint alleges that defendants omitted relevant prior art—published studies disclosing that ustekinumab was effective in treating ulcerative colitis. ECF No. 36 ¶¶ 125 (Spanish study), 127 (German study), 128 (Swiss study). There is an important distinction between material and cumulative prior art. *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1333 (Fed. Cir. 2009). The Federal Circuit has emphasized that when distinguishing between the two it is "necessary to explain both 'why' the withheld information is material . . . and 'how'

an examiner would have used this information in assessing the patentability of the claims." *Exergen Corp.*, 575 F.3d at 1329–30 (citation omitted).

Here, the Amended Complaint alleges that the patent examiner initially denied all the patent's claims because NCT 236 rendered them either anticipated or obvious. ECF No. 36 ¶ 141. It further alleges that the patent examiner would have used these three additional published studies disclosing that ustekinumab was effective in treating ulcerative colitis when deciding whether the patent was obvious or anticipated. Put differently, the Amended Complaint alleges that the omitted prior art went to the dispositive issue—the why—and that the patent examiner would have used these published studies disclosing that ustekinumab was effective in treating ulcerative colitis when deciding the issue—the how. Thus, plaintiffs sufficiently allege that the omissions were material.

Whether the Amended Complaint sufficiently alleges intent is a more difficult question. The Federal Circuit has repeatedly stated that "to find a prosecution omission fraudulent there must be evidence of intent separable from the simple fact of omission." *Dippin' Dots*, 476 F.3d at 1347. Because it is rare to have direct evidence of deceptive intent, especially at the pleading stage, "a district court may infer intent from indirect and circumstantial evidence." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (citation omitted).[10] For an inference to be

[10] Fraud on the PTO arises in two forms: when a party asserts it alleging antitrust liability, like the instant case and when a defendant asserts inequitable conduct as an equitable defense in a patent infringement action. Prior to 2011, the Federal Circuit drew a sharp distinction between the two. *See Nobelpharma AB*, 141 F.3d at

reasonable, it must be plausible and "flow logically from the facts." *Exergen Corp.*, 575 F.3d at 1329 n.5.

Ultimately, the Amended Complaint alleges sufficient facts for the Court to make a reasonable inference of specific intent to deceive the PTO. But it is by no means a slam dunk. The Amended Complaint does not specifically allege that defendants had actual knowledge of the relevant prior art.[11] Rather, the Court must infer it from the surrounding circumstances. *See Therasense*, 649 F.3d at 1290 ("[A] district court may infer intent from indirect and circumstantial evidence."). The Court

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1070 (explaining that inequitable conduct serves as a "shield" whereas "*Walker Process* fraud is a more serious finding of fraud [that] potentially exposes a patentee to antitrust liability and thus serves as a sword"). Because the Federal Circuit viewed *Walker Process* fraud as "a more serious offense than inequitable conduct," it applied a higher standard for materiality and intent. *Id.*

That changed in 2011 when the Federal Circuit addressed the "problems created by the expansion and overuse of the inequitable conduct doctrine" in *Therasense*. There, the Federal Circuit noted that over time courts had applied lower standards for intent and materiality and then proceeded to raise those standards to match *Walker Process* fraud. *Therasense*, 649 F.3d at 1290–91; *see TransWeb, LLC v. 3 M Innovative Properties Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016) ("After *Therasense*, the showing required for proving inequitable conduct and the showing required for proving the fraud component of *Walker Process* liability may be nearly identical."). The impact of this shift for the Court is that post-*Therasense* cases analyzing inequitable conduct may be instructive on *Walker Process* fraud.

[11] Plaintiffs point to two facts in their response in opposition: (1) the relationships between defendants and the authors of the various studies, and (2) that defendants disclosed at least one of the studies in its analogous European patent. ECF No. 57 at 24. The problem for plaintiffs is that neither fact is actually alleged in the Amended Complaint. *See* ECF No. 36. Consequently, the Court cannot consider these facts when deciding the motion to dismiss.

can do so from the following facts: the published studies involved research concerning one of J&J's most profitable drugs, ECF No. 36 ¶ 2, and that the studies implicated research that J&J's own scientists were conducting clinical trials on, *id.* ¶ 120. Combined with the allegations that J&J did not disclose its own clinical study until the patent examiner located it, and its awareness that the PTO was concerned about obviousness and anticipation because the patent examiner had denied the application on these grounds, these facts are sufficient to push this claim over the finish line.

The procedural posture of the case is doing a lot of heavy lifting for plaintiffs. At this stage of the litigation, the Court is required to accept the facts as alleged in the Amended Complaint as true and to make all reasonable inferences in favor of plaintiffs. Because of the standard of review, it is uncommon for these fact-intensive questions to be resolved at this early juncture. *See In re Effexor XR Antitrust Litig.*, No. 3:11-cv-5479, 2014 WL 4988410, at *26 (D.N.J. Oct. 6, 2014) *rev'd and remanded on other grounds by In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017) (because intent to defraud is "usually an issue of fact that should not be resolved on a pretrial motion," dismissal is appropriate only when "the [p]laintiff has failed to allege any facts that can support an inference of bad faith or an intent to deceive"); *WebXchange Inc. v. Dell Inc.,* No. 1:8-cv-132, 2010 WL 256547, at *3 (D. Del. Jan. 20, 2017) (stating that "factual determinations about the extent" of the alleged knowledge of the withheld information or whether the information was "intentionally withheld from the PTO are not appropriate" when resolving as motion to dismiss); *see also Nobelpharma AB*, 141 F.3d at 1059 (deciding on a post-trial motion that the

plaintiffs failed to adequately allege intent to deceive the PTO); *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996) (same); *California Inst. of Tech. v. Broadcom Ltd.*, No. 2:16-cv-3714, 2019 WL 8807748, at *7–8 (C.D. Cal. July 1, 2019) (deciding the issue on summary judgment).

In sum, the Court finds that plaintiffs have sufficiently alleged *Walker Process* fraud as to the omission of the Spanish, German, and Swiss studies, but not as to the misrepresentations of NCT 236.

b. The Acquisition of the Momenta Patents

The Court now turns to defendants' acquisition of the Momenta patents. The allegations in the Amended Complaint relating to the acquisition are summarized as follows: In 2020, defendants acquired Momenta in its entirety, including its patent portfolio. ECF No. 36 ¶ 162. At the time of the acquisition, defendants had monopoly power in the United States market for ustekinumab. *Id.* ¶ 163. The patent portfolio included four patents covering technologies used to manufacture biosimilars. *Id.* ¶ 162. These technologies can be employed to manufacture a biosimilar that is more likely to obtain an "interchangeability" determination from the FDA. *Id.* ¶ 164. An interchangeable determination is valuable for biosimilar manufactures because it allows consumers in some states to change prescriptions without a doctor's visit. *Id.* ¶ 50. Defendants themselves acknowledged that a competitor took "full advantage of [Momenta's] inventions" to "make as close a copy to [Stelara] as possible." *Id.* ¶ 164. However, defendants are not biosimilar manufacturers. *Id.* ¶ 167. Rather, defendants make branded biologic products. *Id.* Thus, defendants had no procompetitive use with respect to ustekinumab, or other products. *Id.* ¶ 165.

Defendants argue that the lawful acquisition of a patent cannot constitute an antitrust violation as a matter of law.[12] ECF No. 46 at 12–13; ECF No. 65 at 3–7. The law is clear, however, that there are circumstances where the acquisition of patents can constitute an antitrust violation. *See Ford Motor Co.*, 405 U.S. at 576 n.11; *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act.") (citations omitted); *United States v. Singer Mfg. Corp.*, 374 U.S. 174, 194–95 (1963) (finding an antitrust violation for a competitor to transfer a patent to another

[12] Defendants argue—without citing any case law—that because neither the Federal Trade Commission ("FTC") nor the Department of Justice ("DOJ") challenged defendants' acquisition of Momenta and allowed it to proceed without conditions, the plaintiffs' claim fails as a matter of law. ECF No. 46 at 12–13. But, several courts, including at least one in this circuit, have allowed these claims to go forward. *Intellectual Ventures I LLC v. Cap. One Fin. Corp.*, 99 F. Supp. 3d 610, 627 (D. Md. 2015); *ABS Global, Inc. v. Inguran, LLC*, No. 3:14-cv-503, 2016 WL 3963246 (W.D. Wis. July 21, 2016); *SCM Corp.*, 645 F.2d at 1206–07. The Supreme Court itself has acknowledged the importance of private enforcement of antitrust laws. *See Perma Life Muffles, Inc. v. Int'l Part Corp.*, 392 U.S. 134, 139 (1968) *overruled on other grounds by Copperweld Corp. v. Indep. Tube Corp.*, 461 U.S. 752 (1984) ("[A]ntitrust laws are best served by ensuring that the private action will be an ever-present threat to deter anyone contemplating business behavior in violation of the antitrust laws."). Plainly, defendants' argument that the acquisition of the Momenta patents does not run afoul of the antitrust laws simply because neither the FTC nor DOJ challenged the acquisition is inconsistent with the law. *See ABS Global*, 2016 WL 3963246, at *19 n.12 (stating that "contrary" to the defendant's "assertion" the plaintiff "could, as it did, elect to challenge [the defendant's] patent accumulation under § 2 of the Sherman Act"); United States Dep't of Justice & Federal Trade Commission, Antitrust Guidelines for Licensing of Intellectual Property §§ 3.14, 5.7 (Jan. 2017) ("An acquisition of intellectual property may lessen competition" and "may be assessed under section 7 of the Clayton Act, [and] sections 1 and 2 of the Sherman Act.").

competitor to "achieve the common purpose of enforcement" to "suppress" competition). But the point at which the acquisition of patents becomes anticompetitive is unclear. In the absence of definitive guidance from the Fourth Circuit, this Court will find that a monopolist's acquisition of exclusive rights to patents related to the subject matter of the monopoly can constitute anticompetitive conduct as a matter of law.

This conclusion is consistent with the relevant case law. In *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981), the Second Circuit held that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *Id.* at 1206. However, the Second Circuit stated in dicta that "[p]atent acquisitions are not immune from the antitrust laws. Surely a [§] 2 violation will have occurred where, for example, the dominant competitor in a market acquires a patent covering a substantial share of the same market that [they] know[] when added to [their] existing share will afford [them] monopoly power." 645 F. 2d. at 1205.

The Second Circuit further opined that "analyzing the lawfulness of the acquisition of a patent necessitates [a] primar[y] focus upon the circumstances of the acquiring party and the status of the relevant product and geographic markets at the time of the acquisition." *SCM Corp.*, 645 F.2d at 1207. Specifically, "in scrutinizing patents under § 2 of the Sherman Act, the focus should be on the market power that will be conferred by the patent in relation to the market position acquired by the acquiring party." *Id.* at 1208.

The United States District Court for the District of Maryland distinguished *SCM Corp.* in *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 99 F. Supp. 3d 610 (D. Md. 2015). The District of Maryland found that, unlike in *SCM Corp.* where the patent acquisition preceded the relevant market, the relevant party in its case "had no role in the market when they began their patent acquisition, and the products already were in place and employed by the banking industry." *Intellectual Ventures I LLC*, 99 F. Supp. 2d at 627. Thus, the court concluded that the party "alleged sufficiently that [the p]laintiffs willfully acquired their monopoly power" and allowed the § 2 claim to proceed because it "would not be futile." *Id.* In other words, the District of Maryland concluded that patent acquisition can, by itself, constitute anticompetitive conduct when it is used to acquire or attempt to acquire monopoly power.[13]

Also citing *SCM Corp.*, the United States District Court for the District of Massachusetts held that "the acquisition of patents can constitute monopolization when the dominant competitor in a market acquires a patent covering a substantial share of the same market." *Bio-Rad Labs., Inc.*, 483 F. Supp. 3d at 63. The court

[13] When deciding the subsequent motion for summary judgment, the District of Maryland stated in dicta that "the exercise of monopoly power with regard to a single patent (or even a few patents) usually does not offend antitrust law." *Intellectual Venture I LLC v. Cap. One. Fin. Corp.*, 280 F. Supp. 3d. 691, 698 (D. Md.). The court then distinguished that scenario from "acquir[ing] a vast portfolio of patents that are essential to technology employed by an entire industry." *Id.* The court ultimately decided the motion for summary judgment on *Noerr-Pennington* immunity and collateral estoppel grounds.

ultimately found the alleged anticompetitive harm "unavailing because the alleged acts are not actually anticompetitive." *Id.* at 64.

Importantly, the District of Massachusetts's decision on the § 2 claims turned on whether monopoly power was sufficiently alleged. For two of the three alleged markets, the court dismissed the § 2 claim because the party either "d[id] not allege that [the antitrust defendant] had anything close to monopoly power (or even significant market power) . . . at the time of its merger," *Bio-Rad Labs., Inc.*, 483 F. Supp. 3d at 64, or "failed [to] plausibly allege that [the antitrust defendant] is an actual monopolist in the [relevant market] either now or at the time of . . . acquisition," *id.* at 65. However, for the third market, the antitrust plaintiff alleged that the defendant "possess[ed] a 90% market share at the time of the acquisition" and that the acquisition "further increased its market share." *Id.* at 67. The District of Massachusetts found that allegation "sufficient to allege a Sherman Act violation because it indicates that a dominant competitor further entrenched its monopoly by consolidating its hold on the market." *Id.*

The United States District Court for the Western District of Wisconsin also found that the antitrust plaintiff sufficiently alleged that the defendant's "acquisition of patents may qualify as unlawful under the Sherman Act." *ABS Global Inc. v. Inguran, LLC*, No. 3:14-cv-503, 2016 WL 3963246, at *18 (W.D. Wis. July 21, 2016) (citations omitted). In doing so, the court found the following facts persuasive. First, that the antitrust defendant had not made use of the patent despite acquiring it eight years prior. *Id.* Second, that the antitrust defendant brought a lawsuit against a

competitor on eleven patents, two of which were acquired. *Id.* Finally, that the defendant acquired an exclusive license "comprising 46 U.S. patents" resulting in it "either owning or having exclusive rights to a portfolio of 136" related patents. *Id.* at 18. Importantly, the Western District of Wisconsin emphasized that "acquiring and asserting a valid patent is absolutely protected by the patent laws 'in the absence of monopoly but, because of their tendency to foreclose competitors from access to markets or customers or some other inherently anticompetitive tendency, they are unlawful under § 2 if done by a monopolist.'" *Id.* at 17. (quoting *City of Mishawaka, Ind. v. American Elec. Power Co., Inc.*, 616 F.2d 976, 986 (7th Cir. 1980)).

This Court's conclusion is also consistent with the Sherman Act's purpose. The purpose of antitrust laws is to preserve competition, which necessarily requires discouraging practices that make it hard for consumers to buy at competitive prices. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962) (stating that antitrust law is concerned "with the protection of *competition*, not *competitors*") (emphasis added). It is easy to see how a monopolist's acquisition of exclusive rights over processes to make competitor goods—as is the case here—has the potential to harm competition. It can exclude rivals from the market. Put differently, the acquisition of a patent related to the subject matter of the monopoly has the effect of increasing or prolonging the monopolist's market power because competitors cannot use the patented invention. That is anticompetitive.

Of course, there are circumstances where acquiring patents in a related field can be procompetitive because it enables innovation. Erik Hovenkamp and Herbert

Hovenkamp, *Buying Monopoly: Antitrust Limits on Damages for Externally Acquired Patents*, 25 Tex. Intell. Prop. L. J. 39, 54–55 (2017) ("[P]atent laws permit and even encourage the development of market shifting innovations that might serve to give the inventor substantial market power.") It may very well be true that defendants had a procompetitive reason for acquiring Momenta and its patent portfolio, and at a later stage of the litigation, defendants may pursue this argument. At this stage, however, viewing the allegations in the light most favorable to plaintiffs, the Amended Complaint sufficiently alleges that the acquisition of the Momenta patents was anticompetitive.

Consistent with the decisions of other courts that have addressed this question, this Court finds that allegations that a monopolist acquired exclusive rights in a patent related to the subject matter of the monopoly can constitute anticompetitive conduct. *See also* 14 Philip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 707a (2024) (stating that a basic conclusion regarding patent acquisition is that "[a]cquisition by a monopolist of exclusive rights in related patents should presumptively be a § 2 exclusionary practice, and this applies with equal force to the acquisition of a firm that owns such patents") (quotation marks omitted). Specifically, the Court finds the following allegations sufficient: first, defendants are monopolists; second, defendants acquired exclusive rights in four patents covering some of the processes used to make biosimilars; third, defendants are not biosimilar producers; and fourth, defendants asserted the acquired patents in subsequent litigation.

c. Material and Substantial Cause

Anticompetitive conduct alone does not establish a monopolization claim. A plaintiff must also connect that anticompetitive conduct to a corresponding antitrust injury. *See Crawl Space Door Sys., Inc. v. SmartVent Prods., Inc.*, 2020 WL 13691776, at *5 (E.D. Va. Apr. 8, 2020) (stating that for conduct to be exclusionary "a monopolist's act must have an anticompetitive effect" and it "must harm the competitive process and thereby harm consumers") (quotation marks and citation omitted). Plaintiffs are required to show that defendants' antitrust violation was a but-for and material cause of the alleged injury. *In re Zetia (Esetimibe) Antitrust Litig.*, 655 F. Supp. 3d 406, 430 (E.D. Va. 2023). Thus, the Amended Complaint must allege that the enforcement of the '307 patent and acquisition of the Momenta patents caused a biosimilar to delay its entry into the market, and as a result, plaintiffs were required to pay higher prices for ustekinumab. The Court finds that it does.

The Amended Complaint sufficiently alleges that together the '307 patent and the Momenta patents kept at least one biosimilar producer off the market. *See* ECF No. 36 ¶ 196 (detailing how J&J used two of these patents to move for a preliminary injunction against Amgen). On November 3, 2022, Amgen announced that it had submitted its Phase 3 clinical trial to the FDA. ECF No. 36 ¶ 187. And on November 7, 2022, Amgen informed J&J that it intended to market its biosimilar not earlier than 180 days from the date of the notice. *Id.* ¶ 188. The Amended Complaint alleges that the defendant brought a lawsuit alleging infringement of the '307 patent and the Momenta patents. *Id.* ¶ 195. Amgen entered a settlement with defendants that delayed its entry until January 2025. *Id.* ¶ 199. The FDA approved Amgen's

biosimilar on October 31, 2023; however, Amgen has delayed entry because of its settlement agreement with defendants. *Id.* ¶ 200. These facts are sufficient to allege causation at this stage of the litigation.

Defendants lodge a series of causation arguments all of which quickly unravel under scrutiny. They first argue that "the mere enforcement of patents under the BPCIA has no exclusionary effect." ECF No. 46 at 29–30. Essentially, defendants believe that because the BPCIA does not have an automatic stay provision and allows for an at-risk launch, the assertion of the patents in litigation cannot exclude any biosimilar. *Id.* at 13. Defendants' argument is built upon the faulty assumption that conduct is not exclusionary simply because the law does not *require* a biosimilar to delay its entry. It is quite easy to see how the "mere enforcement of patents" would lead a biosimilar manufacturer to delay its entry—patent litigation is extremely expensive. And biosimilar manufacturers are businesses that necessarily weigh the costs of prolonged litigation against the costs of settling or delaying entry. The biosimilar manufacturer's decision to delay its entry does not break the causal chain. *See Zenith Radio*, 395 U.S. at 114 n.9 ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden . . . .").

Next, defendants argue that "plaintiffs have failed to plead any facts showing that, if the '307 patent had never been issued, the competitive landscape would have been any different"—that the "patent by itself is not alleged to be the cause of any actual biosimilar exclusion." ECF No. 46 at 29. This argument introduces a

requirement that does not exist in the law—that the alleged conduct be the exclusive cause of harm. Defendants' conduct must be a material and but-for cause of the harm; however, it does not need to be the *sole* cause. *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 98 (2d Cir. 2017); *see Zenith Radio*, 395 U.S. at 114 n.9.

Finally, defendants argue that the alleged use of their patents to settle with biosimilar manufacturers is not an actionable source of alleged anticompetitive behavior.[14] ECF No. 46 at 22. The Court finds *Amphastar Pharmaceuticals Inc. v. Momenta Pharmaceuticals, Inc.*, 850 F. 3d. 52 (1st Cir. 2017), instructive. There, the United States Court of Appeals for the First Circuit addressed the question of whether litigation can constitute antitrust injury if an independent antitrust violation exists. That court joined others in recognizing that the institution of litigation "could furnish the source of antitrust injury . . . even if it could not provide the basis for a Sherman Act violation under the *Noerr-Pennington* doctrine." *Id.* at 57 (quoting *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d F.2d 1552, 1561 (11th Cir. 1992)). Put differently, there is a distinction between antitrust *liability* and antitrust *injury*. *Noerr-Pennington* stands for the proposition that litigation enforcing lawfully acquired patents cannot serve as a basis for antitrust liability. It does not, however, serve as a bar to asserting that patent enforcement litigation constitutes antitrust injury.

[14] To the extent defendants argue that the enforcement of the '307 patent cannot constitute a basis for antitrust liability, the Court's conclusion that the Amended Complaint sufficiently alleges a *Walker Process* fraud claim forecloses that argument.

Here, plaintiffs' basis for antitrust *liability* is the acquisition of the Momenta patents. And the enforcement lawsuits only constitute antitrust *injury*. Thus, *Noerr-Pennington* does not bar plaintiffs' claims. *McGuire Oil*, 958 F.2d at 1564 (finding that litigation is not antitrust injury when there was no separate predicate anticompetitive act); *Premier Elec. Constr. Co. v. National Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 372–76 (7th Cir. 1987) (determining that the cost of fighting litigation could constitute sole antitrust injury when the litigation resulted from a separate Sherman Act violation); *Hynix Semiconductor Inc. v. Rambus, Inc.*, 527 F. Supp. 2d. 1084, 1097 (N.D. Cal. 2007) (concluding that "where the patent litigation is used to further the harm caused under a more traditional antitrust theory, a plaintiff should be allowed a full recovery") (quotation marks omitted).

The procedural posture of the case helps plaintiffs here too. At this stage of the litigation, the Amended Complaint need only show that it was "reasonably probable" that the alleged violations caused their injury. *Va. Vermiculite, Ltd. v. W.R. Grace & Co.-Conn.*, 156 F.3d 555, 540 (4th Cir. 1998). This low standard "is particularly justified in this context because in antitrust cases, where the proof is largely in the hands of the alleged conspirators, dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Id.* (quoting *Hospital Bldg. Co. v. Trustees of the Rex Hosp.*, 425 U.S. 738, 746 (1976)). It is possible that one or more of these arguments may turn out to be barriers to plaintiffs' causation theory at later stages of the litigation, but they do not mandate dismissing the Amended Complaint now.

B. State Law Claims—Antitrust, Consumer Protection, and Unjust Enrichment

Defendants make various arguments concerning why the Court should dismiss plaintiffs' state-law claims.[15] As threshold matters, defendants aver that all of plaintiffs' state-law claims are preempted by federal law, ECF No. 92 at 24–27, and that plaintiffs lack Article III standing in the states where no named plaintiff resides or purchased Stelara, ECF No. 46 at 37.[16] As to the antitrust claims, defendants argue that they fail for the same reasons as the federal claims, including lack of standing to bring a *Walker Process* fraud claim. *Id.* at 35–36. Defendants then lodge

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[15] Defendants raise several challenges to the state-law claims in the Appendix attached to their motion to dismiss. ECF No. 46 at 40 (asserting that "[p]laintiffs' state[-]law claims suffer from a variety of [] defects" that are "detailed in J&J's accompanying Appendix"); ECF No. 46-3 (appendix). Pursuant to E.D. Va. Civ. R. 7(F)(3), briefs must not exceed 30 pages "except for good cause shown in advance of filing." Defendants' opening brief is 29 pages. ECF No. 92. And an appendix that contains substantive arguments is not an "affidavit" or "supporting documentation" that can be excluded from the page limit. E.D. Va. Civ. R. 7(F)(3). Defendants never asked leave to file a brief exceeding the local rules' page limit. Had they done so, the Court would have certainly considered the request, given the complexity of this case. But because defendants did not comply with the local rules, the Court will not entertain any substantive arguments raised only in the appendix.

[16] Defendants appear to concede that whether plaintiffs can bring class-wide state-law claims in states where there are no alleged purchases is an issue for class certification, not a motion to dismiss. ECF No. 65 at 25 (citing *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 134 (4th Cir. 2021)). Therefore, consistent with Fourth Circuit law, the Court will not address the merits of the state-law claims brought under Alaska, Arkansas, Puerto Rico, Rhode Island, or Wyoming law, because there is a factual dispute as to whether plaintiffs purchased the branded drug at supra-competitive prices in those jurisdictions. *Mayor of Baltimore*, 995 F.3d at 126.

a challenge under Fed. R. Civ. P. 8 and 9(b) to the sufficiency of plaintiffs' consumer protection claim pleadings. *Id.* at 37–38. Finally, defendants argue that the unjust enrichment claims must be dismissed in several states because they cannot be used as a workaround to the states' antitrust laws. *Id.* at 36. The Court will address each argument in turn.

i. Preemption

The Federal Circuit[17] has developed a conduct-based approach to determine whether state laws conflict with federal patent law and are preempted. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1336 (Fed. Cir. 1998) *overruled in part on other grounds by Market Indus. Inc. v. Karavan Trailer Inc.*, 175 F.3d 1356, 1360–61 (Fed. Cir. 1999) (en banc)); *see In re DDAVP Indirect Purchaser Litig.*, 903 F. Supp. 2d. 198, 215–17 (S.D.N.Y. 2012) (summarizing the Federal Circuit's relevant preemption jurisprudence). *Hunter Douglas Inc.* identifies two relevant categories of conduct "that patent law immunizes from state tort liability:" (1) conduct entirely before the PTO, unless it amounts to fraud and (2) publicization of a patent, unless done in bad faith. *Hunter Douglas, Inc.*, 153 F.3d at 1335–36.

Defendants believe that *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), rather than *Hunter Douglas* controls. ECF No. 101 at 17–19. Their reliance is misplaced. The Supreme Court in *Buckman* held that the Federal Food

[17] When determining whether federal patent law preempts state-law claims, Federal Circuit law controls. *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH,* 524 F.3d 1254, 1260 (Fed. Cir. 2008).

Drug, and Cosmetic Act ("FDCA") preempted the plaintiffs' state-law tort claims for the defendants' fraudulent representations to the Federal Drug Administration ("FDA") to obtain approval to market bone screws. 531 U.S. at 343. The Supreme Court reasoned that the plaintiffs' claim did not rely on traditional state tort law principles independent of federal regulations. *Id.* at 350–53. Rather, the plaintiffs relied on the anti-fraud provisions of the FDCA itself. *Id.*; *see also Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1356 (Fed. Cir. 2013) (distinguishing the plaintiff's claims on the grounds that "*Buckman* involved a claim based on fraud before the FDA, which existed . . . 'solely by virtue of the FDCA disclosure requirements'") (quoting *Buckman*, 531 U.S. at 352–53). Therefore, the plaintiffs' claims were more akin to enforcing the FDCA. *Buckman*, 531 U.S. at 353. Importantly, the FDA was "empowered to investigate suspected fraud . . . [and] respond to fraud by seeking injunctive relief and civil penalties, . . . [and] thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud on the Administration." *Id.* at 349. And the Supreme Court was concerned with FDA applicants having to "comply[] with the FDA's detailed regulatory regime in the shadow of the 50 States' tort regimes." *Id.* at 350.

Defendants aver that *Buckman* stands for the proposition that *all* claims of fraud on a federal agency are preempted. This Court—consistent with the others that have addressed the issue—disagrees. Courts interpreting *Buckman* have refined the contours of its holding. Relevant to this case is the important distinction between claims where fraud on an agency is sufficient to impose liability and "freestanding

allegations of wrongdoing apart from the defendant's purported" fraud. *Desiano v. Warner-Lamber & Co.*, 467 F.3d 85, 95 (2d Cir. 2006), *aff'd by an equally divided court sub nom.* 552 U.S. 440 (2008) (*per curium*); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d at 219–20. *Buckman* controls only to the former. *See In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (explaining that in *Buckman*, "[t]he plaintiff's claims, which existed solely by virtue of the FDCA disclosure requirement, failed because they were based not on traditional state law regulations of health and safety, but solely on the relationship between the federal agency and the regulated entity") (cleaned up).

Here, plaintiffs' state-law claims require allegations apart from fraud on the PTO: Antitrust claims require a showing of anticompetitive conduct, consumer protection requires proof of consumer deception, and unjust enrichment requires proof of enrichment upon a defendant that would be inequitable to accept and retain. Nor is fraud a required element of any of the state-law claims. Evidence of fraud may be relevant to such a claim, and it may serve to strip defendants of immunity from antitrust liability, but it is not an element of any of the state-law causes of action. Therefore, *Buckman* is inapplicable to this case.

Because the Court finds that the Amended Complaint plausibly alleges that defendants procured the '307 patent through fraud, this case falls squarely within

the first *Hunter Douglas* category.[18] Thus, consistent with Federal Circuit law, plaintiffs' state-law claims are not preempted.

ii. Antitrust Claims

Plaintiffs bring antitrust claims—monopolization and attempted monopolization—under the laws of Alabama, Arizona, California, Connecticut, the District of Columbia, Florida, Hawai'i, Illinois,[19] Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. Each state

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[18] To the extent defendants argue that plaintiffs need to allege additional misconduct in the marketplace, the Federal Circuit's use of the disjunctive "or" forecloses that argument. *Hunter Douglas, Inc.*, 153 F.3d at 1336 ("federal patent law bars the imposition of liability for conduct before the PTO unless the plaintiff can show that the patentholder's conduct amounted to fraud *or* rendered the patent application process a sham") (emphasis added).

[19] Defendants argue that the Illinois Antitrust Act class-action bar prevents plaintiffs from bringing an indirect purchaser class action in federal court. The relevant provision states that "no person shall be authorized to maintain a class action in any court of the State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General." 740 Ill. Comp. Stat. 10/7(2). Courts are split on whether the class-action bar applies in federal court. *Compare In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 371 (D.R.I. 2019) *with In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F. Supp. 3d 418, 434 (E.D. Va. 2019). At least one court in this district has found that the class action bar in Illinois does not apply in federal court because of its plain language or because Fed. R. Civ. P. 23 governs class actions in federal court. *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-md-2836, 2019 WL 1397228, at *26 (E.D. Va. Feb. 6, 2019) *R. & R. adopted by* 400 F. Supp. 3d. at 434. This Court, too, concludes that the Illinois Antitrust Act class-action bar does not apply in federal court.

interprets their antitrust laws in harmony with federal law.[20] ECF No. 36 ¶¶ 338–374. The Court will first address whether plaintiffs have antitrust standing to assert a *Walker Process* fraud claim and then will address the elements of the remaining claims.

a. Antitrust Standing for Walker Process *fraud claims*

In *Illinois Brick*, the Supreme Court barred indirect-purchaser plaintiffs from seeking damages under federal antitrust law. 431 U.S. at 730–33. Several states, however, have enacted *Illinois Brick* repealer statutes that enable indirect-purchaser

[20] *See, e.g.*, Ariz. Rev. Stat. § 44-1412; Conn. Gen. Stat. Ann. § 35-44b; D.C. Code § 28-4515; 740 Ill. Comp. Stat. 10/11; Iowa Code § 553.2; Md. Code Ann., Com. Law § 11-202; Mich. Comp. Laws § 445.784(2); Neb. Rev. Stat. § 59-829; Nev. Rev. Stat. § 598A.050; N.H. Rev. Stat. Ann. § 356:14; N.M. Stat. Ann. § 57-1-15; Or. Rev. Stat. § 646.715(2); R.I. Gen. Laws § 6-36- 2(b); S.D. Codified Laws § 37-1-22; Utah Code Ann. § 76-10-3118; Vt. Stat. Ann. Tit. 9, § 2453(b); W.Va. Code § 47-18-16; *City of Tuscaloosa v. Harcos Chems. Inc.*, 158 F.3d 548, 555 n. 8 (11th Cir. 1998); *Chavez v. Whirlpool Corp.*, 113 Cal. Rptr. 2d 175, 179 (Cal. App. 2 Dist. 2001); Haw. Rev. Stat. Ann. § 480-3; *Orr v. BHR, Inc.*, 4 F. App'x 647, 651 (10th Cir. Feb. 16, 2001) (unpublished); *Tri-State Rubbish, Inc. v. Waste Mgmt., Inc.*, 875 F. Supp. 8, 14 (D. Me. 1994); *Minn. Twins P'ship v. State*, 592 N.W.2d 847, 851 (Minn. 1999); *NAACP v. Claiborne Hardware Co.,* 393 So. 2d 1290, 1301 (Miss. 1980), *rev'd on other grounds*, 458 U.S. 886 (1982); *People v. Rattenni*, 613 N.E.2d 155, 158 (N.Y. 1993); *Rose v. Vulcan Materials Co.*, 194 S.E.2d 521, 530 (N.C. 1973); N.D. Op. Atty. Gen. 81-35 (Apr. 2, 1981); *Caribe BMW, Inc. v. Bayerische Motoren Werke Aktiengesellschaft*, 19 F.3d 745, 754 (1st Cir. 1994); *State ex rel. Leech v. Levi Strauss & Co.*, 1980 WL 4696, at *2 n.2 (Tenn. Ch. Sept. 25, 1980); *Grams v. Boss,* 294 N.W.2d 473, 480 (Wis. 1980), *overruled on other grounds* by *Meyers v. Bayer AG, Bayer Corp.*, 735 N.W.2d 448 (Wisc. 2007); *see also In re Pre-Filled Propane Tank Antirust Litig.*, No. 14-cv-2567, 2019 WL 4796528, at *8-11 (W.D. Mo. Aug. 21, 2019); *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 545 (N.D. Ill. 2019); *Flovac, Inc. v. Airvac, Inc.*, 84 F. Supp. 3d 95, 105 (D.P.R. 2015), *aff'd*, 817 F.3d 849 (1st Cir. 2016).

plaintiffs to bring antitrust claims for damages under state law. *See California v. ARC Am. Corp.*, 490 U.S. 93, 103 (1989) (concluding that "nothing in *Illinois Brick* suggests that it would be contrary to congressional purposes for States to allow indirect purchasers to recover under their own antitrust laws").

There is an important distinction between *Illinois Brick* and antitrust standing. *See McCready*, 457 U.S. at 476 (stating that the "restrictions on the § 4 remedy recognized in . . . *Illinois Brick*" is "analytically distinct" from the "conceptually more difficult question 'of which persons have sustained injuries *too remote* from an antitrust violation to give them standing to sue for damages'") (quoting *Illinois Brick*, 431 U.S. at 728 n.7) (alterations accepted). Put simply, *Illinois Brick* is a restriction on recovery—it is not an antitrust standing doctrine. Therefore, just because a plaintiff is barred from recovering under *Illinois Brick* does not mean that they lack antitrust standing.

The inverse is also true: Just because a plaintiff is not barred from recovery under *Illinois Brick* does not mean they automatically have antitrust standing.[21] Therefore, the fact that several states have removed an absolute bar to recovery for indirect purchasers does not mean the Court is relieved of its obligation to ensure that plaintiffs have antitrust standing. *See, e.g., Lorix v. Crompton Corp.*, 736

[21] Plaintiffs chastise defendants for importing the rationale from *Illinois Brick* onto the standing question because these are "analytically distinct" questions. ECF No. 98 at 9–10. But then plaintiffs appear to want the Court to collapse the "analytically distinct questions" and conclude that states enacting *Illinois Brick* repealer statutes confers antitrust standing to indirect purchasers. *Id.* at 14–15. Plaintiffs cannot have it both ways.

N.W.2d. 619, 630 (Minn. 2007) ("The real difficulty lies in defining the outer limits of indirect[-]purchaser standing in Minnesota."); *Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So.2d 331, 344 (Miss. 2004) (finding indirect purchasers' claims too remote to establish antitrust standing). Thus, plaintiffs must show that they have antitrust standing. *In re Interior Molded Doors Antitrust Litig.*, 2019 WL 4478734, at *13.

First, the Court must determine the appropriate antitrust standing test for each claim. "It is axiomatic that in determining state law a federal court must look first and foremost to the law of the state's highest court . . . ." *Assicurazioni Generali, S.pA. v. Neil*, 160 F.3d 997, 1002 (4th Cir. 1998). If the state's highest court has not addressed the issue, federal courts must predict how the state's highest court would rule. *See Wells v. Liddy*, 186 F.3d 505, 528 (4th Cir. 1999) (directing courts to consider "canons of construction, restatements of the law, treatises, recent pronouncements of general rules or policies by the state's high court, well considered dicta, and the state's trial court decisions"). With these principles in mind, the Court turns to determining and then applying the appropriate antitrust standing test with respect to plaintiffs' state antitrust claims.[22]

[22] Florida allows indirect purchasers to bring actions under its consumer protection statute for antitrust violations. *Mack v. Bristol Myers Squibb Co.*, 673 So. 2d. 100, 108 (Fla. Dist. Ct. App. 1996) (finding that relevant provisions of the consumer protection statute reflect a "clear statement of legislative policy to protect consumer through the authorization of such indirect[-]purchaser actions" for antitrust violations). To be successful, a plaintiff must establish a deceptive act or unfair practice that caused actual damages. *Stewart Agency, Inc. v. Arrigo Enters., Inc.*, 266

1. States applying the AGC *test*

The Court finds that Alabama, Arizona, California, Connecticut, the District of Columbia, Illinois, Iowa, Kansas, Maryland, Michigan, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, and Wisconsin either explicitly apply the factors from *AGC* or use a substantially similar test.[23] *AGC* instructs courts to look at five factors to determine antitrust standing:

So. 3d. 207, 212 (Fl. Dist. Ct. App. 2019). The Amended Complaint sufficiently alleges each required element. ECF No. 36 ¶¶ 375–93.

[23] The Iowa, Nebraska, and Nevada Supreme Courts have adopted the *AGC* factors. *Southhard v. Visa U.S.A., Inc.*, 734 N.W. 2d 192, 198–99 (Iowa 2007); *Kanne v. Visa U.S.A. Inc.*, 723 N.W.2d 293, 301 (Neb. 2006); *Nevada Recycling & Salvage, Ltd. v. Reno Disposal Co., Inc.*, 423 P.3d 605, 607 (Nev. 2018). The Connecticut and Mississippi Supreme Courts have applied factors that parallel the *AGC* test. *Tremont Pub. Advisors, LLC v. Conn. Res. Recovery Auth.*, 217 A.3d 953, 966 (Conn. 2019) ("We conclude therefore, that, to have standing to bring a claim under the antitrust act, a plaintiff must adequately plead both that it has suffered an antitrust injury and that it is an efficient enforcer of the antitrust act."); *Owens Corning*, 868 So. 2d 331, 344 (Miss. 2004) (finding that a plaintiff lacked antitrust standing under Mississippi law because its injuries were too remote and were not "injur[ies] of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful").

Appellate courts in California, New Mexico, and New York have applied the *AGC* factors. *In re Interior Molded Doors Antitrust Litig.*, 2019 WL 4478734, at *16 (summarizing relevant California state law); *Nass-Romero v. Visa U.S.A.*, 279 P.3d 772, 776 (N.M. Ct. App. 2012); *Ho v. Visa U.S.A., Inc.*, 793 N.Y.S.2d 8, 8–9 (N.Y. App. Div. 2005). Therefore, the Court will defer to these decisions and apply *AGC* to these claims.

Trial courts in the District of Columbia, Michigan, Vermont, and Wisconsin have applied the *AGC* factors. *Peterson v. Visa U.S.A.*, No. 3-cv-8080, 2005 WL 1403761, at *4–5 (D.C. Sup. Ct. Apr. 22, 2005); *Stark v. Visa U.S.A. Inc.*, 2004 WL 1879003, at *4 (Mich. Cir. Ct. July 23, 2004); *Fucile v. Visa U.S.A., Inc.*, No. 3-cv-1560, 2004 WL 3030037, at *3 (Vt. Super. Ct. Dec. 27, 2004); *Strang v. Visa U.S.A., Inc.*, No. 3-cv-11323, 2005 WL 14003769, at *2–*5 (Wis Cir. Ct. Feb. 8, 2005). Each jurisdiction has harmonization provisions, and as a result, federal courts have applied *AGC* to these claims. *In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, No. 1:9-cv-3690, 2015 WL 3988488, at *10(N.D. Ill. June 29, 2015); *Oliver v. Am. Express Co.*, No. 1:19-cv-566, 2021 WL 386749, at *3, 5 (E.D.N.Y. Feb. 1, 2021). Thus, the Court is persuaded that the highest courts in these jurisdictions would apply the *AGC* test.

Federal courts have applied *AGC* to antitrust claims brought under Illinois, Kansas, New Hampshire, South Dakota, Tennessee law. *O'Regan v. Arbitration Forums, Inc.*, 121 F.3d 1060, 1062-63 (7th Cir. 1997) (Illinois); *In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, 2015 WL 3988488, at *8–9 (Kansas); *Donovan v. Dig. Equip. Corp.*, 883 F. Supp. 775, 785 (D.N.H. 1994) (New Hampshire); *Oliver*, 2021 WL 386749, at *4 (South Dakota); *In re Interior Molded Doors Antitrust Litig.*, 2019 WL 4478734, at *16 (Tennessee). This Court will join the others and apply *AGC* to these claims.

No court in Alabama, Arizona, Maryland, North Dakota, Oregon, Utah, or West Virginia has provided a clear statement laying out an antitrust test. However, each state has a harmonization provision. *McCluney v. Zap Prof'l Photography*, 663 So. 2d 922, 926 (Ala. 1995) (stating that "the federal law relating to monopolization governs Alabama antitrust actions"); Ariz. Rev. Stat. § 44-1412; *Oliver*, 2021 WL 386749, at *3 (recognizing Maryland's harmonization provision), *7 (same, for North Dakota); Or. Rev. Stat. § 646.715(2); Utah Cd. §§ 76-10-3109(1)(a); W. Va. Code St. R. § 142-9-2. The presence of these harmonization provisions—and the absence of any countervailing law—persuades the Court that the application of the *AGC* factors is appropriate. *In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, 2015 WL 3988488, at *4 ("The Court is persuaded that the presence of a statutory harmonization provision (either statutory or common law), absent any countervailing statutory law or case law from a state appellate court, is sufficient to permit a district court to apply federal antitrust-standing law—including *AGC*—to claims brought under that state's antitrust laws.") (emphasis removed).

> (1) the causal connection between an antitrust violation and harm to the plaintiffs, and whether that harm was intended;
>
> (2) whether the harm was of a type that Congress sought to redress in providing a private remedy for violations of the antitrust laws;
>
> (3) the directness of the alleged injury;
>
> (4) the existence of more direct victims of the alleged antitrust injury; and
>
> (5) problems of identifying damages and apportioning them among those directly and indirectly harmed.

Kloth v. Microsoft, 444 F. 3d 312, 324 (4th Cir. 2006) (citing *AGC*, 459 U.S. at 537–545) (quotation marks and citations omitted). The first two factors address whether the alleged harm is the correct type of injury, whereas the latter three factors focus on whether the plaintiff is the proper party. Given this overlap, several courts have truncated the analysis to whether the plaintiff has suffered an antitrust injury and is an efficient enforcer. *See Todorov*, 921 F.2d at 1449 (finding "this two-pronged approach . . . endorsed by the Supreme Court" in *Cargill*, 479 U.S. at 110 n.5). Because this Court has already concluded that plaintiffs have suffered an antitrust injury, *supra* Part II.A.ii.a.i, the analysis here will focus solely on whether plaintiffs are efficient enforcers.

The Court notes that *Illinois Brick* and *AGC* pose analytically distinct questions yet significantly overlap. *Int'l Bhd. of Teamster, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 825–28 (7th Cir. 1991) (stating that *Illinois Brick* and *AGC* are "analytically distinct" and are "independent obstacle[s] to recovery"). Both relate to the directness of the alleged injury and express concern

with duplicative recovery. Because *AGC* incorporates *Illinois Brick*, the fact that some states have rejected *Illinois Brick* but apply *AGC* creates a tension in the law—especially because a broad application of *AGC* could effectively negate the state's rejection of *Illinois Brick*. Therefore, the Court will apply the *AGC* factors but will keep in mind that states that have enacted an *Illinois Brick* repealer statute have taken action to differentiate their antitrust law from their federal counterpart.

The first efficient-enforcer factor—the directness of the injury—weighs in favor of finding standing. Directness requires a showing that the alleged antitrust injury was the direct result of the anticompetitive conduct. *In re Online DVD Rental Antitrust Litig.*, No. 4:09-cv-2029, 2011 WL 1629663, at *7 (N.D. Cal. Apr. 29, 2011). Plaintiffs' standing argument is based on the theory that absent defendants' enforcement of its unlawfully acquired patents, at least one biosimilar would have entered the market and lowered the price of ustekinumab. In other words, the price of ustekinumab would have been lower had defendants competed fairly in the market. It is true that plaintiffs' injury is not as direct in the *Walker Process* fraud context as it would be in a typical indirect-purchaser case because the conduct does not automatically produce the alleged injury—it requires successful enforcement of the patent. However, because the high price of ustekinumab is the end goal of the alleged anticompetitive conduct, this factor weighs in favor of standing.

The second efficient-enforcer factor—the existence of more direct victims—favors denying standing. Plaintiffs point to several cases where states have found standing for indirect purchasers in drug delay cases and highlight the importance of

considering the *Illinois Brick* repealer statutes. ECF No. 98 at 17. Specifically, plaintiffs point to *In re Suboxone (Burprenorphien Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d. 665 (E.D. Pa. 2014), to suggest that this factor carries less weight in *Illinois Brick* repealer states because "[s]trict application of this factor, in the context of indirect purchasers, would always caution against standing, an outcome incompatible with the purposes of *Illinois Brick* repealer statutes." *Id.* (quoting *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d at 698).

Plaintiffs' argument, however, ignores a critical difference between a typical indirect-purchaser lawsuit and a *Walker Process* fraud claim brought by an indirect purchaser: the existence of the patent infringer as a victim. In typical indirect-purchaser lawsuits, only one class of more direct victims exists: the direct purchasers. However, indirect-purchaser *Walker Process* fraud claims differ because there are two classes of more directly harmed victims: the direct purchasers *and* the patent infringers.[24]

Because it is closer in the casual chain, the patent infringer is necessarily in a better position than an indirect purchaser to evaluate whether to enforce the antitrust laws. An infringer knows whether the suspected patent prevented it from entering the relevant market and knows its ability to work around a patent, whereas an indirect purchaser can only speculate. And unlike direct consumers, who can pass

[24] The fact that plaintiffs bear the brunt of the alleged injury does not change the fact that the anticompetitive conduct was directed at the patent infringers. In other words, even though the end goal was plaintiffs' overcharge payments, all the alleged anticompetitive conduct was directed at patent infringers.

on the harm to indirect purchasers, patent infringers will often have the self-interest to enforce the antitrust laws because they also experience the harm of the anticompetitive conduct. In fact, most *Walker Process* claims arise as counterclaims in patent infringement lawsuits. *In re DDAVP Direct Purchaser Litig.*, 585 F.3d at 689–90 ("*Walker Process* claims are based on a fraudulently obtained patent and are typically brought as counterclaims in patent infringement suits . . . ."). Because of patent infringers' self-interest, the risk of an antitrust violation going unremedied is much lower for *Walker Process* claims than in the typical indirect-purchaser cases.[25] Thus, the second factor weighs in favor of denying standing. *AGC*, 459 U.S. at 542 ("The existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a more remote party . . . to perform the office of a private attorney general.").

[25] The Court notes that patent infringers' self-interest will not always align with consumers' self-interest. In the instances where an alleged patent infringer opts not to pursue their interests for strategic reasons, antitrust laws may go unenforced. The Second Circuit highlighted this same concern when refusing to *per se* bar consumers from bringing *Walker Process* fraud claims. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d at 691 ("This asks too much of generic competitors and other potential patent challengers, who may not have the strategic interest or the resources to start or win such a battle, or who may be presented with strong incentives to settle their challenge by patent holders seeking not only to preserve their patents' enforceability, but also to avoid potential *Walker Process* liability."). The Second Circuit's point is important and persuasive. However, it was dealing with a case brought by direct purchasers *not* indirect purchasers. Therefore, ruling that direct purchasers could not bring the lawsuit meant that *only* a patent infringer could bring the claim. That is not the case here.

The Court agrees that typically these concerns carry little weight in the standing analysis in states with *Illinois Brick* repealers. *See In re Suboxone Antitrust Litig.*, 64 F. Supp. at 697–98. However, in the *Walker Process* context these considerations carry more force. Because *Walker Process* fraud claims sit at the junction between the patent and antitrust laws, courts are necessarily required to balance the two. Of course, the Supreme Court made clear in *Walker Process* itself that "the interest in protecting patentees from innumerable vexatious suits [should not] be used to frustrate the assertion of rights conferred by the antitrust laws." 382 U.S. at 176 (quotation marks omitted). That does not, however, mean courts cannot or should not weigh these factors when attempting to strike the proper balance between these two competing areas of law. In a situation where there are multiple patent infringers and direct purchasers who are better suited to enforce the antitrust laws, this Court finds denying standing to more remote indirect purchasers strikes the appropriate balance.

The final factor—the speculative nature of the damages—also favors denying standing. Proof of consumer damages in the *Walker Process* context has the potential to be very speculative. For plaintiffs to succeed on their overcharge claim, they would need to address—among other things—whether the price for ustekinumab would have been lower, what the competitor's price for it would have been, and how many competitors would have entered the market and what effect that would have on the price had the alleged anticompetitive conduct not occurred. This is a rather complex

and speculative world that plaintiffs find themselves in, which diminishes the justification for granting standing.

In sum, the balance of the factors weighs against finding standing in the states that apply the *ACG* standard. To be clear, the Court is not saying that indirect purchasers will always lack standing to bring a *Walker Process* fraud claim for damages under state law. The Court is saying that based on these facts—where there are direct consumers and multiple patent infringers better positioned to enforce the antitrust laws, and where the plaintiffs' damages are highly speculative—plaintiffs lack standing. Therefore, the Court finds that plaintiffs lack standing to bring a *Walker Process* fraud claim under the laws of Alabama, Arizona, California, Connecticut, the District of Columbia, Illinois, Iowa, Kansas, Maryland, Michigan, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and Wisconsin.

2. States applying alternative tests

Hawai'i, Maine, Minnesota, and North Carolina either apply a more liberal version of *AGC* or a different test all together. The Court will assess plaintiffs standing under each.

Hawai'i — No Court in Hawai'i has expressly applied the *AGC* factors. *Davis v. Four Seasons Hotel Ltd.*, 228 P.3d 303, 324 n.33 (Haw. 2010) ("[T]his court has not expressly applied the *AGC* analysis to unfair methods of competition claims arising under" the state's antitrust laws). However, the Hawai'i Supreme Court has

recognized that to establish antitrust standing there must be a direct injury. *Haw. Med. Ass'n v. Haw. Med. Serv. Ass'n, Inc.*, 148 P.3d. 1179, 1206 (Haw. 2006). The focus of the standing inquiry, therefore, is on the directness of the injury. *Id.* Because the Court has concluded that the directness of plaintiffs' alleged injury favors granting standing, plaintiffs have standing to bring a *Walker Process* fraud claim under Hawai'i law.

Maine — A Maine trial court held that "[i]t is probable that the Maine Law Court . . . would look to the [*AGC*] factors in determining standing under Maine's antitrust laws and would apply those factors except to the extent those factors cannot be reconciled with the legislature's adoption of the *Illinois Brick* repealer." *Knowles v. Visa U.S.A.*, No. CV-2003-707, 2004 WL 2475284, at *5 (Me. Super. Ct. Oct. 20, 2004). Specifically, the court found that "[i]n light of the Maine's *Illinois Brick* repealer, . . . directness or remoteness of the asserted injury [] should be disregarded entirely in any injury as to standing under Maine's antitrust laws." *Id.* at *6. The court proceeded to analyze "the prudential concerns" including whether the damages are complex and speculative and whether there is a danger of duplicative recoveries. *Id.* Given that directness is the only *AGC* factor that weighs in favor of granting plaintiffs standing, the Court finds that plaintiffs do not have standing to bring a *Walker Process* fraud claim under Maine law.

Minnesota — Minnesota has explicitly declined to apply *AGC* to its antitrust laws. *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 628 (Minn. 2007). In doing so, the court noted that "the Minnesota antitrust law contains an expansive grant of

standing designed to protect Minnesota citizens from sharp commercial practices." *Id.* at 627 (quotation marks and citation omitted). Despite that statement, the court went on to explain that "[s]tanding under Minnesota antitrust law must be defined by some prudential limits informed by foreseeability, proximate cause, remoteness, and relation of the injury to the purpose of the antitrust law." *Id.* at 631. It then held that the indirect-purchaser plaintiff had standing because "she is an end user of a consumer good whose price was inflated by anticompetitive conduct earlier in the chain of manufacture," and that "as an end user, [she] is the party most likely to be injured by an anticompetitive overcharge because she is the only party in the chain of purchase who cannot pass on part or all of that overcharge." *Id.* Here, the plaintiffs—who bought a product indirectly, like the plaintiff in *Lorix*—sustained an injury that is foreseeable, not remote, and directly related to the purpose of the antitrust law. Because the plaintiffs' injury falls within the prudential limits governing Minnesota's antitrust law, the Court finds that the plaintiffs have standing to bring their Minnesota claims.

North Carolina — A North Carolina trial court adapted *AGC* into a five-factor test for antitrust standing. *Crouch v. Compton Corp.*, Nos. 02 CVS 4375, 03 CVS 2514, 2004 WL 2414027, at *18–19 (N.C. Super. Ct. Oct. 26, 2004). These factors include:

> (1) whether the plaintiff is a consumer or competitor in the allegedly restrained market,
>
> (2) the directness of the impact on the plaintiff,
>
> (3) whether there exist other indirect purchasers in the distribution who are more directly impacted,
>
> (4) the speculative nature of the damage claims, and

> (5) the risk of duplicative recovery and danger complex apportionment of damages.

Id. In the absence of any contrary authority, the Court will use the factors laid out in *Crouch* to determine whether plaintiffs have antitrust standing. *Cf. Teague v. Bayer AG*, 671 S.E.2d 550, 556–57 (N.C. Ct. App. 2009) (rejecting application of *AGC* to the specific facts of that case).

Plaintiffs brought ustekinumab from distributors, so they qualify as consumers in the allegedly restrained market. Factors two and three overlap with the third and fourth *AGC* factors. However, there is one important difference: The North Carolina court is only concerned with whether there are more directly harmed indirect purchasers. Because patent infringers are not indirect purchasers, their existence does not impact the analysis here. Thus, factors two and three weigh in favor of finding standing.

The last two factors overlap with the fifth *AGC* factor. However, the North Carolina court made clear "that these factors are limited by the General Assembly's creation of indirect purchaser standing." *Crouch*, 2004 WL 2414027, at *19. The main concern is ensuring that there "only be one fund constituting the amount of the alleged overcharge to North Carolina residents" and that "the courts must guard against multiple liability for the fund and prejudice to absent victims or non-class members." *Id.* Here, too, the existence of the patent infringer does not impact this factor because the infringer is not a victim of the overcharge, which is the main concern. Because each factor weighs in favor of granting standing, the Court finds

that plaintiffs have standing to bring a *Walker Process* fraud claim under North Carolina law.

c. Remaining Elements

The Court must now determine whether the Amended Complaint sufficiently alleges the remaining elements of the surviving state antitrust claims. Because each state has enacted a harmonization provision, for the reasons stated in Part III.A, the Court finds that the Amended Complaint has sufficiently alleged monopoly power and that the acquisition of the Momenta patents can constitute exclusionary conduct. However, in the states where plaintiffs do not have standing to bring a *Walker Process* fraud claim, defendants are immune from antitrust laws when enforcing the '307 patent. *See Nobelpharma AB*, 141 F.3d at 1068. In other words, the enforcement of the '307 patent cannot constitute the basis for antitrust liability. Because plaintiffs cannot claim that the enforcement of the '307 patent violated the antitrust laws, it may constitute an intervening cause of the alleged antitrust injury. *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, 545 F. Supp. 3d 922, 983 (D. Kan. 2021) (finding that an intervening cause can break the causal chain).

The existence of an intervening cause is an affirmative defense. *See In re Flonase Antitrust Litig.*, 798 F. Supp. at 628 ("When a defendant relies upon the existence of an independent cause, however, such cause must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury."). A court does not ordinarily consider affirmative defenses when deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6).

However, "in the relatively rare circumstances where facts sufficient to rule on an affirmative defense are alleged in the complaint, the defenses may be reached by a motion to dismiss filed under [Fed. R. Civ. P.] 12(b)(6)." *Goodwin v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir. 2007) (en banc). In other words, a court may exercise its discretion and consider affirmative defenses that "clearly appear on the face of the complaint." *Id.* (cleaned up).

Because the Amended Complaint alleges that defendants asserted both the '307 and the Momenta patents in its enforcement litigation, it appears on the face of the Amended Complaint that enforcement of the '307 patent could constitute an intervening cause of the antitrust injury plaintiffs allege arises from the Momenta patents. Therefore, out of an abundance of caution, the Court will assess, based solely on the face of the Amended Complaint, whether the '307 patent breaks the causal chain. The Court finds, for the purposes of the motion to dismiss, that it does not.

An intervening cause "breaks the causal connection between the alleged antitrust violation and the plaintiff's injury" if it "fully accounts for the plaintiff's alleged injury." *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, 545 F. Supp. 3d at 983; *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011). The Amended Complaint alleges that defendants used both the '307 patent and the Momenta patents in subsequent enforcement litigation to keep biosimilars off the market. ECF No. 36 ¶ 196. Therefore, for enforcement of the '307 patent to break the causal chain, it would need to be able to

foreclose the market for ustekinumab from competitors irrespective of the Momenta patents.

It is not clear from the facts as alleged in the Amended Complaint whether enforcement of the '307 patent alone could keep ustekinumab competitors off the market. The Amended Complaint does not assert that the '307 patent covered all uses of ustekinumab; it claims only that the patent covered using ustekinumab to treat ulcerative colitis. ECF No. 36 ¶ 132. The Amended Complaint further maintains that the drug was used to treat several other conditions, including Crohn's disease, plaque psoriasis, and psoriatic arthritis. *Id.* ¶ 269. Put differently, plaintiffs allege that ustekinumab is used to treat multiple diseases and that the '307 patent covered only one of those uses. Thus, the affirmative defense of an intervening cause does not, on the face of the Amended Complaint, defeat the remaining claims as a matter of law. *See In re Flonase Antitrust Litig.*, 798 F. Supp. at 628 ("When a defendant relies upon the existence of an independent cause, however, such cause must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury.") (quotation marks and citation omitted).

In other words, whether enforcement of the '307 patent breaks the causal chain is a question of fact, and the possibility that defendants could succeed on their affirmative defense does not defeat the claims at this stage in the litigation. Recall, the Amended Complaint need only show that it was "reasonably probable" that the alleged violations caused their injury. *Va. Vermiculite, Ltd.*, 156 F. 3d at 540. And the Fourth Circuit has instructed that dismissals prior to discovery "should be granted

very sparingly." *Id.* It is possible that the '307 patent may turn out to be a barrier to plaintiffs' causation theory, but it does not mandate dismissing the Amended Complaint now.

In sum, the Court finds that plaintiffs do not have standing to bring a *Walker Process* fraud claim under the laws of Alabama, Arizona, California, Connecticut, the District of Columbia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and Wisconsin. However, because the Amended Complaint sufficiently alleges that the acquisition of the Momenta patents was anticompetitive, and it is not clear based on the facts alleged that the '307 patent is an intervening cause of the alleged injury, the Court will deny the motion to dismiss as to all the state antitrust claims.[26]

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[26] The confluence of the Federal Circuit's preemption doctrine and each state's antitrust standing doctrine has produced two possible outcomes in the *Walker Process* fraud context: Either state courts can invalidate a patent, or plaintiffs can bring a claim under state law that they cannot bring under federal law but can only be filed in federal court.

The first outcome seems to run headlong into 28 U.S.C. § 1338, which vests federal courts with exclusive jurisdiction to hear cases "arising under" the patent laws. The Federal Circuit has waffled on whether *Walker Process* fraud claims invoke its exclusive jurisdiction. The Federal Circuit has dealt with numerous *Walker Process* fraud claims. *E.g.*, *Nobelpharma AB,* 141 F.3d at 1068; *Dippin' Dots, Inc.*, 476 at 1346–47. Yet, in *Xitronix Corp. v. KLA-Tencor Corp.*, 882 F.3d 1075 (Fed. Cir. 2018), the Federal Circuit initially ruled that it did not have jurisdiction and transferred the case to the United States Court of Appeals for the Fifth Circuit. *Id.* at 1075–76. However, the Fifth Circuit disagreed and transferred the case back to the Federal Circuit. *Xitronix Corp. v. KLA-Tencor Corp.,* 916 F.3d 429, 431 (5th Cir. 2019). The

iv. Consumer Protection

Plaintiffs bring consumer protection claims under the laws of Alabama, Alaska, Arizona, Arkansas, California, the District of Columbia, Florida, Georgia, Illinois, Indiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wyoming.

Defendants move to dismiss plaintiffs' state-law claims on the grounds that the allegations in the Amended Complaint are inadequate under Fed. R. Civ. P. 8 or 9(b). The Amended Complaint contains just over 84 pages of factual allegations that serve as the basis for plaintiffs' asserted claims. ECF No. 36. It then incorporates

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Federal Circuit accepted the transfer but noted its disagreement and stated that the order was not precedential. *Xitronix Corp. v. KLA-Tencor Corp.*, 757 Fed. App'x 1008, 1008–09 (Fed. Cir. Mar. 14, 2019) (unpublished). The Federal Circuit revived this dispute with the Fifth Circuit in *Chandler v. Phoenix Servs. L.L.C.*, 1 F.4th 1013 (Fed. Cir. 2021). There, the Federal Circuit transferred the appeal to the Fifth Circuit and noted that the patent at issue had already been deemed unenforceable. *Id.* at 1018. The Fifth Circuit ultimately accepted jurisdiction but noted its disagreement with the Federal Circuit over which court has appellate jurisdiction over *Walker Process* fraud claims. *Chandler*, 45 F.4th at 809. All of this is to say that it is not clear whether *Walker Process* fraud claims "arise under" the patent laws. However, it seems extremely odd for state courts—whose decisions can only be reviewed by the Supreme Court on direct review—to be able to invalidate a patent.

But the second outcome seems equally bizarre. Ultimately, however, it is beyond the authority of this Court to refuse to apply binding precedent in an effort to harmonize these seemingly disparate doctrines. The role of district courts is to determine facts and then apply legal principles to those facts. This Court is not free to ignore precedent even when following existing law produces an odd result, as is the case here. Put simply, this oddity is worth the attention of the higher courts.

those factual allegations by reference, *id.* ¶ 375, and includes the specific statutes defendants allegedly violated, *id.* ¶ 392. Defendants' argument is that plaintiffs have directed their factual allegations to the antitrust claims and, in conclusory fashion, stated that the same facts are actionable under several states' consumer protection laws. ECF No. 46 at 37–38. Courts are split on this issue. Some have dismissed claims for listing state laws without pleading how the elements are satisfied, and others have found such allegations sufficient to place the defendants on notice of the conduct claimed. *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 359–360 (D.R.I. 2017) (summarizing split).

This Court finds that neither Fed. R. Civ. P. 8 nor 9(b) requires that a plaintiff plead specific facts for each element rather than incorporating by reference the factual allegations. Fed. R. Civ. P. 8 requires a "short and plain statement of the claim showing that the pleader is entitled to relief," to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. It is hard to see how detailed factual allegations and a list of the specific state statutes defendants allegedly violated fail to put defendants on notice of plaintiffs' claims. Thus, the Court finds that plaintiffs have properly pleaded their state-law consumer protection claims. *Blue Cross and Blue Shield of Vt. V. Teva Pharm. Indus., Ltd.*, No. 5:22-cv-159, 2024 WL 323775, at *43–44 (D. Vt. Jan. 22, 2024) (finding that a complaint sufficiently alleged state unjust enrichment claims for Fed. R. Civ. P. 8 purposes when it incorporates detailed factual allegations); *In re Zetia (Ezetimibe)*

Antitrust Litig., No. 2:18-md-2836, 2019 WL 1397228, at *35 (E.D. Va. Feb. 6, 2019) *R. & R. adopted by* 400 F. Supp. 3d. at 441 (same).

Defendants lodge two additional arguments specifically at plaintiffs' Illinois and Massachusetts claims. Essentially, defendants believe that because plaintiffs cannot bring antitrust claims in those states, they cannot use the consumer protection laws as an end-run around the antitrust laws. First, the Illinois Supreme Court has refused to allow a plaintiff to use its consumer protection laws to bring an antitrust claim where there is no cause of action under the Illinois Antitrust Act. *Laughlin v. Evanston Hosp.*, 550 N.E.2d 986, 993 (Ill. 1990). However, the Court has concluded that the Amended Complaint has plausibly alleged an antitrust claim under Illinois law. *Supra* Part III.B.ii. Because plaintiffs' consumer protection claim is not "inconsistent with the legislative intent manifested in the Illinois Antitrust Act," the Court will deny the motion to dismiss the Illinois consumer protection claim. *Siegel v. Shell Oil Co.*, 480 F. Supp. 2d 1034, 1048 (N.D. Ill. 2007).

Second, plaintiffs bring their Massachusetts claim under Mass. Gen. Laws ch. 93A, §§ 1, *et seq*, which supplies a cause of action to "[a]ny person, other than a person entitled to bring a claim under [Mass. Gen. Laws ch. 93A, § 11]." Mass. Gen. Laws ch. 93A, §9. ECF No. 36 ¶ 392(m). "The state legislature has extended *Illinois Brick*'s prohibition on suits by indirect purchasers to § 11 of Massachusetts' consumer protection law, but not § 9." *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d at 700. Because plaintiffs bring their claim under § 9, not § 11, *Illinois Brick* is not applicable.

ECF No. 57 at 30 n. 109. Thus, the Court will deny the motion to dismiss the Massachusetts consumer protection claim on these grounds.

iv. Unjust Enrichment

Plaintiffs bring unjust enrichment claims under the laws of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawai'i, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

Defendants move to dismiss the unjust enrichment claims brought under Connecticut, Delaware, Georgia, Idaho, Illinois, Kentucky, Louisiana, Maryland, Massachusetts, Missouri, Montana, New Jersey, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, Washington, and Wyoming law because these states prohibit the use of alternative state-law claims to circumvent *Illinois Brick*. ECF No. 46 at 36. To begin, Connecticut and Maryland each have *Illinois Brick* repealer statutes. Conn. Gen. Stat. § 35-46a(1), Md. Code Com. Law § 11-209(b)(2)(i). Because *Illinois Brick* has no force in these states, the argument that plaintiffs are using unjust enrichment as an end-run around that doctrine fails.

Unjust enrichment laws vary from state to state. It is well established that there are two types of unjust enrichment claims: autonomous and parasitic. *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 411 (S.D.N.Y. 2011) ("In

contemporary United States common law, restitution based upon unjust enrichment takes at least two forms; it may be autonomous or parasitic.") (quotation marks and citation omitted). Autonomous unjust enrichment claims are those that are not derived from a violation of some other state law but rather serve as independent grounds for restitution. *Id.* Whereas parasitic claims—as the name suggests—arise from a violation of another state law. *Id.* Several courts have held that an autonomous unjust enrichment claim may not be used as an end-run around a state's prohibition of indirect purchaser lawsuits pursuant to *Illinois Brick*. *E.g. In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d at 703–04 (collecting cases); *Blue Cross and Blue Shield of Vt. v. Teva Pharm. Indus., Ltd.*, No. 5:22-cv-159, 2024 WL 323775, at *45 (D. Vt. Jan. 22, 2024).

Delaware, Georgia, Idaho, Illinois, Kentucky, Louisiana, Massachusetts, Missouri, Montana, New Jersey, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, and Washington follow *Illinois Brick*. However, plaintiffs sufficiently alleged consumer protection claims under Georgia, Illinois, Massachusetts, Missouri, Montana, South Carolina, Texas, and Virginia law. Therefore, the unjust enrichment claims under those states' laws are not autonomous and do not function as an end-run. *See In re Suboxone Antitrust Litig.*, 64 F. Supp. at 704 (dismissing unjust enrichment claims in states that "have adopted *Illinois Brick* and do not provide a cause of action under either the states' antitrust law or consumer protection law"). Thus, only the autonomous unjust enrichment claims in Delaware, Idaho, Kentucky,

Louisiana, New Jersey, Oklahoma, Pennsylvania, Texas, and Washington will be dismissed.

IV. CONCLUSION

For the foregoing reasons, the Motion to Dismiss (ECF No. 45) filed by Defendants Johnson & Johnson and Janssen Biotech, Inc. is **GRANTED IN PART** and **DENIED IN PART.** Attached to this Memorandum Order and Opinion is an appendix that lays out the judgment as to each claim.

The Motion to Stay filed by Defendants Johnson & Johnson and Janssen Biotech, Inc. (ECF No. 47) is **DENIED AS MOOT.**

Defendants Johnson and Johnson and Janssen Biotech, Inc. are **DIRECTED** to respond to the Amended Complaint within the timeframe prescribed by Fed. R. Civ. P. 12(a)(4).

The Clerk is **DIRECTED** to send a copy of this Memorandum Opinion and Order to all counsel of record.

IT IS SO ORDERED.

/s/
Jamar K. Walker
United States District Judge

Norfolk, Virginia
August 16, 2024

Appendix

Federal Antitrust Claims (Counts 1 & 2)	
Claim	*Judgment*
Count 1 – Monopolization	Claim is not dismissed.
Count 2 – Attempted Monopolization	Claim is not dismissed.

State Antitrust Claims (Counts 3 & 4)[27]	
State	*Judgment*
Alabama	Claims are not dismissed.*
Arizona	Claims are not dismissed.*
California	Claims are not dismissed.*
Connecticut	Claims are not dismissed.*
District of Columbia	Claims are not dismissed.*
Florida	Claims are not dismissed.
Hawai'i	Claims are not dismissed.
Illinois	Claims are not dismissed.*
Iowa	Claims are not dismissed.*
Kansas	Claims are not dismissed.*
Maine	Claims are not dismissed.*
Maryland	Claims are not dismissed.*
Michigan	Claims are not dismissed.*
Minnesota	Claims are not dismissed.
Mississippi	Claims are not dismissed.*
Nebraska	Claims are not dismissed.*
Nevada	Claims are not dismissed.*
New Hampshire	Claims are not dismissed.*
New Mexico	Claims are not dismissed.*
New York	Claims are not dismissed.*
North Carolina	Claims are not dismissed.
North Dakota	Claims are not dismissed.*
Oregon	Claims are not dismissed.*
Puerto Rico	Claims are not dismissed.
Rhode Island	Claims are not dismissed.*
South Dakota	Claims are not dismissed.*
Tennessee	Claims are not dismissed.*
Utah	Claims are not dismissed.*
Vermont	Claims are not dismissed.*
West Virginia	Claims are not dismissed.
Wisconsin	Claims are not dismissed.*

[27] The asterisk represents states where the Court finds that plaintiffs lack antitrust standing to assert a *Walker Process* fraud claim for damages. Therefore, in those states, plaintiffs cannot move forward with the enforcement of the '307 patent as a basis for antitrust liability.

State Consumer Protection Claims (Count 5)	
State	*Judgment*
Alabama	Claim is not dismissed.
Alaska	Claim is not dismissed.
Arizona	Claim is not dismissed.
Arkansas	Claim is not dismissed.
California	Claim is not dismissed.
District of Columbia	Claim is not dismissed.
Florida	Claim is not dismissed.
Georgia	Claim is not dismissed.
Illinois	Claim is not dismissed.
Indiana	Claim is not dismissed.
Maine	Claim is not dismissed.
Massachusetts	Claim is not dismissed.
Michigan	Claim is not dismissed.
Minnesota	Claim is not dismissed.
Missouri	Claim is not dismissed.
Montana	Claim is not dismissed.
Nebraska	Claim is not dismissed.
Nevada	Claim is not dismissed.
New Hampshire	Claim is not dismissed.
New Mexico	Claim is not dismissed.
New York	Claim is not dismissed.
North Carolina	Claim is not dismissed.
Oregon	Claim is not dismissed.
Rhode Island	Claim is not dismissed.
South Carolina	Claim is not dismissed.
South Dakota	Claim is not dismissed.
Tennessee	Claim is not dismissed.
Texas	Claim is not dismissed.
Utah	Claim is not dismissed.
Vermont	Claim is not dismissed.
Virginia	Claim is not dismissed.
West Virginia	Claim is not dismissed.
Wyoming	Claim is not dismissed.

State Unjust Enrichment Claims (Count 6)	
State	*Judgment*
Alabama	Claim is not dismissed.
Alaska	Claim is not dismissed.
Arizona	Claim is not dismissed.
Arkansas	Claim is not dismissed.
California	Claim is not dismissed.
Colorado	Claim is not dismissed.
Connecticut	Claim is not dismissed.
Delaware	Claim is dismissed.
District of Columbia	Claim is not dismissed.
Florida	Claim is not dismissed.
Georgia	Claim is not dismissed.
Hawai'i	Claim is not dismissed.
Idaho	Claim dismissed.
Illinois	Claim is not dismissed.
Iowa	Claim is not dismissed.
Kansas	Claim is not dismissed.
Kentucky	Claim is dismissed.
Louisiana	Claim is dismissed.
Maine	Claim is not dismissed.
Maryland	Claim is not dismissed.
Massachusetts	Claim is not dismissed.
Michigan	Claim is not dismissed.
Minnesota	Claim is not dismissed.
Mississippi	Claim is not dismissed.
Missouri	Claim is not dismissed.
Montana	Claim is not dismissed.
Nebraska	Claim is not dismissed.
Nevada	Claim is not dismissed.
New Hampshire	Claim is not dismissed.
New Jersey	Claim is dismissed.
New Mexico	Claim is not dismissed.
New York	Claim is not dismissed.
North Carolina	Claim is not dismissed.
North Dakota	Claim is not dismissed.
Oklahoma	Claim is dismissed.
Oregon	Claim is not dismissed.
Pennsylvania	Claim is dismissed.
Puerto Rico	Claim is not dismissed.
Rhode Island	Claim is not dismissed.
South Carolina	Claim is not dismissed.
South Dakota	Claim is not dismissed.

Tennessee	Claim is not dismissed.
Texas	Claim is dismissed.
Utah	Claim is not dismissed.
Vermont	Claim is not dismissed.
Virginia	Claim is not dismissed.
Washington	Claim is dismissed.
West Virginia	Claim is not dismissed.
Wisconsin	Claim is not dismissed.
Wyoming	Claim is not dismissed.